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TITLE: Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics And their Environment

PRINCIPAL INVESTIGATOR: Celia P. Kaplan, DrPH, MA

CONTRACTING ORGANIZATION: University of California, San Francisco
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14. ABSTRACT

PURPOSE: Our study comprehensively examined the factors that facilitate or hinder participation in prostate cancer trials by examining patients' attitudes, physicians' perceived barriers, characteristics of prostate trials and sites, and broader community indicators. **SCOPE**: The main objectives were to: a) Conduct telephone interviews with prostate cancer patients (Asian, Black, Latino, and White) identified through the California Cancer Registry (CCR), who were treated at or reside within 60 miles of trial sites to assess their discussions with physicians, intentions and actual participation in prostate cancer clinical trials, attitudes and knowledge about such trials, and barriers to and facilitators of participation, b) Conduct a self-administered survey of the physicians who care for, and were identified by the participating patients as their most influential physician, to determine their typical clinical trial counseling and referral practices, attitudes, and their perceived barriers to and facilitators of patient recruitment, c) Conduct a telephone survey with a research team member (RTM) from each prostate cancer clinical trial site within three regions of the California Cancer Registry (CCR) to assess its cultural competence and outreach efforts, and d) Identify and link clinical trial site community indicators to the clinical trial and patient data collected. **FINDINGS**: The RTM survey indicated RTMS believe that most prostate cancer patients do not participate in clinical trials, particularly minority patients. The patient survey indicated greater patient willingness to participate in a prostate control trial in men with less than a high school education and men with governmental health insurance. The most frequently reported barriers to recruitment were that patients did not understand what participation involved and patients were unable to take time off.

15. SUBJECT TERMS
Clinical trials, minorities, health care settings, communities

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Minorities in Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and Their Environment (W81XWH-09-1-0201)

Celia P. Kaplan, DrPH, MA, Principal Investigator

Annual Report 2011

INTRODUCTION

Randomized clinical trials are the primary experimental approach to determine the effectiveness of new drugs, cancer treatments, and diagnostic procedures.[1] Clinical trial participants receive state-of-the-art cancer care and tend to fare better than those who do not participate.[2] Despite inroads to greater inclusion of minorities in cancer clinical trials,[3-6] recent reports demonstrate lower enrollment among minorities compared to non-Latino Whites (Whites, hereafter).[7] Enhanced participation by minorities is necessary to assess the effectiveness of new prostate cancer treatments in major subpopulations and ensure equity in the distribution of new treatment benefits.

Our study comprehensively examined the factors that facilitate or hinder participation in prostate cancer trials by examining patients' attitudes, physicians' perceived barriers, characteristics of prostate trials and sites, and broader community indicators. Synthesizing these multiple perspectives will facilitate the identification of deficits in the larger system of trial networks, and thus, inform system-wide interventions to increase minority participation in prostate cancer clinical trials.

The main objectives were to: a) Conduct telephone interviews with prostate cancer patients (Asian, Black, Latino, and White) identified through the California Cancer Registry (CCR), who were treated at or reside within 60 miles of trial sites to assess their discussions with physicians, intentions and actual participation in prostate cancer clinical trials, attitudes and knowledge about such trials, and barriers to and facilitators of participation, b) Conduct a self-administered survey of the physicians who care for, and were identified by the participating patients as their most influential physician, to determine their typical clinical trial counseling and referral practices, attitudes, and their perceived barriers to and facilitators of patient recruitment, c) Conduct a telephone survey with a research team member (RTM) from each prostate cancer clinical trial site within three regions of the California Cancer Registry (CCR) to assess its cultural competence and outreach efforts, and d) Identify and link clinical trial site community indicators to the clinical trial and patient data collected.

BODY
The tasks described below represent the timeline and the progress made by the research team:

Task 1: Complete Human Subjects' Institutional Review (Months 1-6) **Completed**
We submitted an application for review and received approval from the UCSF Institutional Review Board (IRB), the Committee on Human Research (CHR). Through the course of our communication with the California Cancer Registry (CCR) we learned that our study had to also undergo formal review and approval by the California State IRB, the Committee for the Protection of Human Subjects (CPHS). We then had to submit a formal Application for Disclosure of Confidential Registry Data with each of the two regional registry agencies we were working with.

Task 2: Identify Clinical Trials (Months 1-6) **Completed**
We identified all 77 active prostate cancer clinical trials being conducted in 2008 in 10 California counties (Alameda, Contra Costa, Los Angeles, Marin, Monterey, San Benito, San Francisco, San Mateo, Santa Clara, and Santa Cruz) through cancer trial search engines. We entered trial information into a Microsoft (MS) Access database.

Task 3: Characterize Clinical Trials and Trial Sites (Months 1-6) **Completed**
Based on the information gathered in Task 2, we entered characteristics of treatment and interventional prostate clinical trials and trial sites into the MS Access database. Clinical trial characteristics included the stage of trial, intervention type, and eligibility/exclusion criteria. Trial site characteristics included full addresses and facility type.

Task 4: *Characterize Clinical Trial Sites and Research Team Members (RTM) (Months 3-14)* **Completed**
Based on the information gathered in Task 2 we identified an RTM associated with each eligible clinical trial site. RTM information (e.g., name, telephone number, and e-mail address) was entered into the MS Access database. The RTM online and telephone surveys were developed based on existing surveys, literature, and discussions with the research team. Data were entered into the MS Access database and statistical analyses were conducted using SPSS software (version 19.0)

Research Team Members and Trial Sites Component. Below is a summary of the major findings from the RTM survey (Appendix 6, Tables 1-4). Surveys were completed with 44 of the 58 RTMs identified at eligible sites.

RTM Survey Respondent Demographics (Table 1). Seventy-three percent of respondent RTMs were female and 68% were born in the United States. The most common job duties were enrolling participants (75%), coordinating and scheduling participant visits (59%), and managing research data (59%). Seven percent of respondents were the leader of a research team as Principal Investigator or Co-Investigator. Over 50% of RTMs interviewed had a graduate education and 61% had worked in research for over ten years.

Clinical Trial Site Characteristics (Table 2). Thirty-nine percent of RTMs felt that none or almost none of the prostate cancer patients in their organization participated in clinical trials. Almost half of RTMs (48%) reported that at least 10% of their prostate cancer clinical trials were insured by Medi-Cal or Medicaid while 14% of RTMs reported that at least 10% of their participants were uninsured. Fourteen percent of RTMs reported that at least 10% of their participants required an interpreter to receive services. Regarding minority participation, 47%, 23%, and 19% of RTMs reported that at least 10% of their participants were Hispanic/Latino, Asian or Pacific Islander, and Black/African American, respectively.

Clinical Trial Site Language Interpretation and Recruitment (Table 3). Seventy-six percent of RTMs reported that someone on their prostate cancer clinical trial team spoke another language well enough to obtain informed consent from study participants. The most common type of language interpretation service offered at trial sites was non-professional interpretation by bilingual staff (100%), followed by professional interpretation by phone (47%), professional interpretation on-site (41%), and professional interpretation via the internet or

video (10%). With respect to providing materials in different languages, over half of sites (54%) offered the Experimental Subject's Bill of Rights to participants in a language other than English, followed by "short form" consent forms (23%), directions to the study site (21%), and appointment reminders (21%). The most common methods of recruitment were presentations to health providers within their organization (68%), posting information about trials on their organization's website (52%), and presenting to outside health providers (21%). Regarding incentives for participants, 36% of RTMs reported that their site offered complimentary or valet parking to prostate cancer clinical trial participants, followed by 21% offering complimentary food or beverages.

RTM Perceived Barriers to Patient Enrollment and Physician Participation (Table 4). The most frequently reported perceived barriers for patients to participate in prostate cancer trials were that patients did not meet eligibility criteria (73%), patients' concerns that the risks of the trial outweigh the benefits (55%), and patients did not understand what clinical trials were (39%). The most frequently reported perceived barriers for physicians to refer or enroll their patients for trials were physicians' concern that patients would not adhere with the study protocols (54%), physicians' concern about the amount of time and effort required to explain trials (33%), and physicians' concern about inadequate reimbursement from trial sponsors (30%).

Task 5: Develop and Refine Instrument for the Patient Telephone Survey (Months 1-15) **Completed**
Based on topics derived from existing surveys, literature, and discussions among the research team, we conducted semi-structured interviews with 11 prostate cancer patients recruited at the urology cancer clinics at UCSF.

The survey was then translated into Spanish and Chinese. To achieve culturally competent and linguistic equivalence, surveys were back-translated into English. Translational discrepancies were discussed and resolved by a group of translators. The patient telephone survey was cognitively pre-tested through phone interviews with 12 participants, focusing on the survey's clarity, consistency, and reliability. Revisions were made accordingly. (Appendix 5)

Task 6: Identify Prostate Cancer Patients and their Attending Physicians (Month 3-16) **Completed**
Patient information from the Northern and Southern CCR was obtained and entered into a MS Access Database. This data included all prostate cancer patients residing in the selected California counties. Patient information from the CCR included the names and hospital affiliations of the patients' attending physicians. MS Access databases were created to track patients' and physicians' information. Given the initially low participation rate (approximately 30%), we requested additional cases from the Northern CCR and Southern CCR.

Task 7: Patient Recruitment and Telephone Survey Administration (Months 16-20) **Completed**
Patients' physicians, as identified by CCR information, were contacted to obtain approval for their patients' participation in the study. Patients, whose physician did not object to their participation, were mailed a letter informing them about the study. Patients who did not refuse to participate were contacted for phone interviews and their responses were entered into a database.

Among the total of 1,869 men were contacted, 685 men refused (35%), 315 men could not be reached (17%), 35 men preferred the other form of the survey (2%), and 855 men responded to the survey (46% participation rate). Of those who responded, 856 men completed interviews in English, Spanish, and Chinese. Data were entered into the MS Access database and statistical analyses were conducted using SPSS software (version 19.0).

Prostate Cancer Patient Component. Below is a summary of the major findings from the patient interview survey (Appendix 6, Tables 5-7).

Patient Survey Respondent Demographics Stratified By Race/Ethnicity (Table 5). Over half of participants (52%) were 65 and older and 76% of patients were married or living with a partner. A lower proportion of

African Americans (60%) reported being married/living with a partner compared to other ethnic groups ($p<0.0001$).

More than half of the participants had a college education (51%). Asian and white participants (74% and 68% respectively) had higher college graduation rates compared to Black and Latino men (35% and 20% respectively) ($p<0.0001$). Close to one third of the participants were foreign born (31%). Significantly more Asians (72%) and Latinos (61%) were foreign born compared to African-Americans (7%) and Whites (11%) ($p<0.0001$). More than half of the participants were employed (part-time or full time). Latinos had the highest proportion of unemployment (54%) compared to other ethnic groups ($p=0.05$). Almost 60% of participants were located in Northern California.

When asked about access to care, over half of the participants responded they had government insurance (52%). Seventy nine percent of participants indicated that they supplemented or had private insurance. White men reported the highest proportion of private health insurance (87%) compared to the other groups ($p<0.0001$).

We also assessed participants' health literacy using a three item, scale-based five point Likert questionnaire validated and tested by Sarkar et al.[8] Responses were averaged to create a health literacy score. Scores were then grouped into three health literacy levels: low (1 through 2.9), medium (3.0 through 4.9) and high literacy (5). Thirty- eight percent of men were classified in the high literacy level. Whites had the highest proportion of high literacy when compared to the other ethnic groups ($p<0.0001$).

The majority of participants had no prior health research experience (74%). A higher proportion of Latinos and Asians indicated that they had never participated in a prior health research study compared to other ethnic groups ($p<0.0001$). With respect to disease characteristics the mean age of prostate cancer diagnosis was 61.5 years (SD=6.4). African-Americans and Latinos (59.9 and 61.1 years) had a statistically significant earlier mean age at diagnosis when compared to whites and Asian American men ($p<0.0001$). Almost 60% of participants had a Gleason score of 7 or higher.

Patients Willingness To Participate In A Prostate Cancer Clinical Trial (Table 6). Willingness to participate in a prostate cancer clinical trial was assessed using a four-point Likert questionnaire developed by the investigators based on prior qualitative work. Men were asked four questions: "In the future, would you participate in a prostate cancer-related clinical trial if offered the opportunity?"; ''If your prostate cancer were to come back or get worse, would you want to participate in a clinical trial?''; "If a family member or a close friend asked for your advice regarding participating in a clinical trial would you recommend participation?"; and "If your doctor asked you to consider participating in any clinical trial, how likely would you be to participate?" Responses were categorized as definitely yes, probably yes, probably not, and definitely not. If a patient responded definitely yes to any of the questions he was defined as "willing to participate in a prostate CCT" and compared to the other categories. Over 38% of the men reported willingness to participate in a cancer clinical trial.

Univariate analysis indicated some significant results in patient willingness to participate in a trial. A greater proportion of Latino men (52%) reported they were willing to participate in a prostate cancer clinical trial while Asian men had the lowest proportion of willingness to participate in a prostate cancer trial (30%) ($p<0.0001$).

Men with less than a high school education level (60%) were more willing to participate in cancer clinical trials compared to participants with higher education levels ($p<0.0001$). Foreign born participants (46%) were more willing to participate in a cancer trial compared to U.S. born participants ($p=.002$).

With respect to access to care, a higher proportion of those with government health insurance (43%) were willing to participate in trials compared to those who did not have government insurance (34%) ($p=0.01$). In contrast, a higher proportion of participants who did not have private health insurance (46%) were willing to participate in a prostate cancer clinical trial compared to those who had private health insurance (36%)

(p=0.02). Participants with low literacy (48%) were more likely to participate in a prostate cancer clinical trial compared to other literacy groups (p=0.03).

Table 7 presents multivariable data on the factors associated with willingness to participate in prostate cancer clinical trials. Latinos were significantly more willing to participate in prostate clinical trials compared to whites (OR=1.8, p=0.01). Men who were employed and men with government insurance (OR 1.7, p=0.01 and OR 1.7, p=0.03, respectively) were also found to be associated with willingness to participate in a prostate trial.

Task 8: Develop and Refine Instrument for the Physician Survey (Months 6-14) **Completed**
The physician survey was developed based on qualitative interviews, existing surveys, literature, and discussions with the research team. The survey was pretested with six physicians and then uploaded to UCSF's Research Electronic Data Capture (REDCap) online program for administration.

Task 9: Physician Recruitment and Survey Administration (Months 24-30) **Completed**
During patient interviews (Task 7), participants were asked for the names of the physicians who were the most influential in their treatment decisions. For patients who stated that no physician was most influential in their treatment decisions, we used the attending physician listed in the CCR database. Contact information for physicians reported as most influential was obtained from the CCR Registry and the American Medical Association (AMA) Physician Masterfile.

Since many of the physicians we planned to recruit for the survey were also sent requests for consent to have their patients participate in the patient telephone survey (Task 7), we delayed administration of the physician recruitment until all such requests were complete; in order to reduce confusion.

Physician survey mailings began in August 2011. We mailed and emailed surveys to 705 physicians reported as the most influential physicians in the patient survey. We received 256 completed surveys (participation rate of 38%), which were entered into the MS Access database and analyzed using SPSS software (version 19.0).

Physician component. Below is a summary of the major findings from the physician interview survey (Appendix 6, Tables 8-11).

Physician survey respondent demographics (Table 8). Ninety-one percent of respondent physicians were male and the majority of physicians were white (61%). More than half of physicians specialized in urology (54%) and 85% graduated from a U.S. medical institution.

Patient and primary practice site characteristics (Table 9). Almost half of physicians practiced in a group/community hospital (47%). Physicians estimated an average of 13% of patients who required language interpretation in order to receive health care services (SD=14.8, median= 10%). For those who required language interpretation services, 20% received professional services by telephone, 18% by non-professional interpretation by bilingual staff, 16% by professional interpretation on-site, and 2% by professional interpretation via the internet or video.

Physician Recruitment and Referral (Table 10). We also asked physicians about how often they have referred or recruited patients into prostate cancer clinical trials. The most common action of referral or recruitment was discussion of the possibility of enrolling in prostate cancer clinical trials (20%), followed by giving patients informational resources about prostate cancer clinical trials (16%), discussion of the potential benefits and risks/burdens of a specific prostate cancer clinical trial (14%), referral to a prostate cancer clinical trial administered by others (11%) and enrolling patients in a prostate cancer control trial where they were the principle investigator or co-investigator (8%).

Physician Perceived Barriers to Patient Enrollment and Physician Participation (Table 11). The following moderate to major barriers were identified when we asked what physicians' perceived barriers to patient enrollment in and physician referrals and recruitments in prostate cancer clinical trials were. The most

frequently reported perceived barriers for patients were that patients did not understand what was involved in participation (70%), patients were unable to take time from work, family, or other duties (51%), and lack of transportation to get to the trial site (45%). The most frequently reported perceived barriers for physicians were physicians' concerns about inadequate information about trials (47%), patients' eligibility or study entry criteria (43%), the inadequate time to dedicate to research (39%), and the amount of time and effort required to explain trials (34%).

Task 10: Identify Community Indicators (Months 12-16) **Completed**

Relevant community indicators were identified based on census data and included in the MS Access database for future analysis. Data will be merged with patient and physician information to determine its influence on recruitment.

Task 11: Data Analysis and Preparation of Final Reports *(Months 30-36)* **Completed**

RTM, patient, and physician surveys will be combined to perform the analysis. A final report and two manuscript drafts will be prepared.

a) Analysis of research team members and clinical trial site characteristics such as language interpretation services at their sites, prostate cancer clinical trial recruitment methods, and incentives for participants.
b) Descriptive analyses of the prostate cancer patient sample: Statistics were calculated and compared across race/ethnicity. Examination of major outcomes included willingness to participate in, knowledge of, and attitudes towards prostate cancer clinical trials.
c) Further analysis of perceived barriers of physician counseling and referral practices in cancer clinical trials

KEY RESEARCH ACCOMPLISHMENTS

- Obtained patient data from both of the participating Registries
- Completed 44 research team member surveys
- Presented preliminary findings of the RTM survey at the 2011 IMPaCT Conference
- Completed 11 semi-structured interviews and 12 cognitive pre-tests of the patient telephone survey
- Completed 856 patient telephone surveys
- Finalized the patient telephone survey and translated the patient telephone survey into Spanish and Chinese
- Conducted preliminary analysis of patient telephone surveys
- Completed six pretests of the physician survey
- Completed implementation of physician survey, 256 physician surveys completed
- Conducted preliminary analysis of physician surveys
- Initiated merging of all databases including patient, physician, site characteristics and community indicators
- Initiated manuscript preparation for publication in peer-reviewed journals

REPORTABLE OUTCOMES

- Kaplan, C., Napoles, A., Gregorich, S., Nguyen, T., & Roach, M. (2011, March). *Assessment of the Clinical Trial Environment in the Recruitment of Minorities into Prostate Cancer Clinical Trials.* Poster session presented at the IMPaCT Conference, Orlando, FL.
- There are two manuscripts currently a manuscript under development (preliminary tittles):
  - Assessing Health Literacy and Willingness to Participate in a Prostate Cancer Clinical Trial Among Minorities in California

- Role of Physicians and Clinical Trial Sites in Recruitment and Participation of Minorities in Clinical Trials

CONCLUSION

Analyses of the research team member, patient and physician surveys suggest common themes among the three main components. Both RTMs and physicians reported low referral and counseling of prostate cancer patients for clinical trials. Although prostate cancer patients report willingness to participate in prostate cancer clinical trials, this was not reflected in their past participation in trials or health research. Latinos, in particular, reported high willingness to participate in clinical trials and African Americans reported similar willingness as whites. These results underscore that minority populations are receptive to participating in clinical trials, challenging current participation statistics. This may also suggest that the limitations in minority participation may be due to the lack of clinical trials information and opportunities, rather than lack of willingness to participate.

Our research has uncovered several perceived barriers to participation in cancer clinical trials. While RTMs indicated physicians' concern that patients would not adhere to study protocols as the main barrier, physicians reported lack of adequate information about clinical trials and concern about patients' study eligibility as the major barriers.

Our results suggest that the clinical trial sites may not be prepared to accommodate minority populations, particularly those with limited English proficiency. Language interpretation was generally available at the sites, but primarily provided by bilingual staff rather than through professional services or interpretation technology systems. Also, clinical trials information was available only in English and participant recruitment efforts were primarily focused on internal presentations rather than community outreach.

The combined data from RTMs, patients, and physicians gathered from this study will be used to inform future intervention studies that aim to increase prostate cancer clinical trial participation, particularly among minorities.

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APPENDIX 1: LIST OF PERSONNEL

List of Personnel receiving pay from the research effort

Investigators:

Kaplan, Celia P.

Gregorich, Steven

Napoles, Anna

Nguyen, Tung

Roach, Mack

Other Personnel:

Choi, Sun-Soon

Duffey, Susan

Herrera, Axel

Hong, Juliette

Lin, Xiao Mei

Navab, Solat

Nuckleach, Dana

Olmos, Tanya

Orea, Gabriela

Pai, Aspah

Quinn, Jessica

Springer, Alana

Yoshida, Maya

Zimmerman, April

Appendix 2: UCSF IRB Approval

University of California
San Francisco

Human Research Protection Program
Committee on Human Research

Notification of Expedited Review Approval

Principal Investigator
Celia P Kaplan
Tung T Nguyen

Co-Principal Investigator
Anna M Napoles, Mack Roach, Steven Gregorich,

Type of Submission: Continuing Review Submission Form
Study Title: Minorities and Clinical Trials: Patients, Clinical Trial Characteristics and their Environment

IRB #: 10-00858
Reference #: 037227

Committee of Record: Parnassus Panel

Study Risk Assignment: Minimal

Approval Date: 01/24/2012 **Expiration Date:** 02/10/2013

Regulatory Determinations Pertaining to this Approval (if applicable):

The requirement for individual HIPAA authorization is waived for some subjects, as detailed in the application. The use or disclosure of the requested information does not adversely affect the rights and welfare of the individuals and involves no more than a minimal risk to their privacy based on, at least, the presence of the following elements:

(1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or if such retention is otherwise required by law;
(3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule;
(4) the research could not practicably be conducted without the waiver; and (5) the research could not practicably be conducted without access to and use of the requested information.

A waiver of the requirement to obtain a signed consent form is acceptable for this study because, as detailed in the application, the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
The waiver applies to some subjects, as detailed in the application.

IRB Comments (if applicable):

All changes to a study must receive CHR approval before they are implemented. Follow the modification request instructions. The only exception to the requirement for prior CHR review and approval is when the changes are necessary to eliminate apparent immediate hazards to the subject (45 CFR 46.103.b.4, 21 CFR 56.108.a). In such cases, report the actions taken by following these instructions.

Expiration Notice: The iMedRIS system will generate an email notification eight weeks prior to the expiration of this study's approval. However, it is your responsibility to ensure that an application for continuing review approval has been submitted by the required time. In addition, you are required to submit a study closeout report at the completion of the project.

Approved Documents: To obtain a list of documents that were approved with this submission, follow these steps: Go to My Studies and open the study – Click on Submissions History – Go to Completed Submissions – Locate this submission and click on the Details button to view a list of submitted documents and their outcomes.

For a list of all currently approved documents, follow these steps: Go to My Studies and open the study – Click on Informed Consent to obtain a list of approved consent documents and Other Study Documents for a list of other approved documents.

San Francisco Veterans Affairs Medical Center (SFVAMC): If the SFVAMC is engaged in this research, you must secure approval of the VA Research & Development Committee in addition to CHR approval and follow all applicable VA and other federal requirements. The CHR website has more information.

Appendix 3: California State IRB (CPHS) Approval

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS
400 R Street, Room 369
Sacramento, California 95811
(916) 326-3660 FAX (916) 322-2512

October 7, 2011

Celia P. Kaplan, DrPH, MA
Division of General Internal Medicine
UCSF
Box # 0856
San Francisco, CA 94143

Project Name: "Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and their Environment"
Project Number: 09-10-03

Dear Dr. Kaplan:

The Committee for the Protection of Human Subjects (CPHS), California Health and Human Services Agency, reviewed and approved your project revisions requested in your correspondence, dated August 25, 2010, for continuation through expedited review. Please refer to the project title and project number above in all future correspondence.

This project is approved for the period of one year. The due date for this project's renewal is **August 31, 2012** if this project is to continue beyond its expiration date of October 5, 2012. Since the CPHS' approval cannot exceed one year pursuant to 45 CFR 46.109(e), CPHS approval will be terminated on the expiration date above unless the CPHS has approved continuation. If CPHS has not approved this project by the renewal date, all research, including data analysis, must stop unless discontinuance will have an adverse impact on research subjects.

Also, if the project is completed or withdrawn it must be submitted to CPHS for approval. Please refer to the CPHS web site (www.oshpd.ca.gov/boards/cphs), "Instructions for Researchers" for submission guidance and deadlines. Although CPHS sends courtesy reminders, it is the Principal Investigator's (PI) responsibility to submit the project renewal on time and to update the CPHS office on changes in the PI and Responsible Official contact information.

Research must be conducted according to the CPHS-approved proposal. CPHS review and approval are required before implementing any changes in your approved study except where necessary to eliminate apparent immediate hazards to human subjects. You are also responsible for the prompt reporting, within 48 hours, to the CPHS of any unanticipated problems or adverse events involving risks to human subjects and others.

If you have any questions, please contact our office at (916) 326-3660 or cphs-mail@oshpd.ca.gov.

Sincerely,

Roxana Killian

Roxana Killian
CPHS Administrator

APPENDIX 4: CCR Approvals

Southern California CCR (CSP) Approval

Northern California CCR (NCCC) Approval

State of California—Health and Human Services Agency
California Department of Public Health

MARK B HORTON, MD, MSPH
Director

ARNOLD SCHWARZENEGGER
Governor

February 25, 2010

Ann Hamilton, PhD.
USC Norris Comprehensive Cancer Center
Keck School of Medicine
Department of Preventive Medicine
1441 Eastlake Ave., Rm. 3427, MC9175
Los Angeles, CA 90089-9175

Dear Dr. Hamilton:

Please find enclosed a copy of a signed approved agreement of disclosure of CCR data for Dr. Celia Kaplan's study with Region 9 of the CCR entitled "Minorities and Clinical Trials: Patients, Physicians, Clinical Trail Characteristics and their Environment."

Sincerely,

Kurt P. Snipes, M.S., Ph.D., Chief
Cancer Surveillance and Research Branch

cc: Ann Brunson

Enclosure

Appendix 3: Confidentiality Agreement for Disclosure of CCR Data

The California Cancer Registry is a repository of cancer incidence data collected by the California Department of Public Health and regional cancer registries throughout the state of California from cancer reporting facilities and health-care providers under the authority of California Health and Safety Code section 103885. CCR data files contain medical and other personal information about identified individuals. By law, CCR data are confidential, and cannot be disclosed except in accordance with strict safeguards.

The University of California at San Francisco has applied to Los Angeles Cancer Surveillance Program for a copy of certain specified CCR data to be disclosed to Celia Kaplan,Dr.PH for the following proposed use: Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and their Environment (CSP #303).

In consideration for the CCR Data Custodian's disclosure of CCR data to Principal Investigator, Recipient Institution and Principal Investigator represent, warrant, and agree as follows:

1. For the purposes of this Confidentiality Agreement:

   "Recipient Institution" means the unit of government, institution, agency, the corporation, or other entity that has requested CCR data, any other unit of government, institution, agency, corporation or other entity that owns or controls the recipient institution or of which the recipient institution is a constituent part, and the directors, officers, employees, consultants, volunteers, students, contractors, agents and associates of the recipient institution.

   "Principal Investigator" means the individual that the recipient institution designated in its request to receive CCR data from the CCR, and who is principally responsible for undertaking the proposed use.

   "CCR data" means all information relating to cases of cancer collected at any time by the California Department of Public Health, a regional cancer registry designated by the Department or any other individual or institution under the authority of California Health and Safety Code Section 103885 and predecessor statutes, whether or not such information identifies an individual or could be used to identify an individual. CCR data also means all documents, files or other records, regardless of format or medium, containing CCR data (whether alone or in combination with other data).

   "Access to data " means the granting of the right to examine data.

   "Disclosure of data" means the granting of the right to examine data and the right to create or retain a copy.

   "Research" has the same definition as 45 CFR Section 46.102(d).

   "Aggregate data" means statistical information derived from CCR data that does not include any individual item of data that represents a person, whether

identified, identifiable or anonymous, and from which no information about an identifiable or anonymous person can be obtained in any manner.

"Reports and statistical information" means reports, articles, special analyses, studies, and other publications and communications that contain aggregate CCR data.

"Sources of information" means hospitals and other facilities or agencies providing diagnostic or treatment services to patients with cancer, and physicians, surgeons, dentists, podiatrists, and all other health care practitioners diagnosing or providing treatment for cancer patients, that have provided information contained in CCR data files.

2. California Health and Safety Code Section 103885 contains various provisions relating to use, access, disclosure, and publication of CCR data. These provisions may be different from the laws, regulations or policies applicable to other data used by Recipient Institution and Principal Investigator. Recipient Institution and Principal Investigator represent and warrant that: (a) they have reviewed section 103885, the California Department of Public Health, Cancer Surveillance and Research Branch, "Policies and Procedures for Access to and Disclosure of Confidential Data from the California Cancer Registry" (www.ccrcal.org) (hereinafter "CCR Data Access and Disclosure Policies"), and the terms and conditions of this confidentiality agreement; (b) they have had a full opportunity to discuss any questions or concerns they may have regarding the interpretation of section 103885 and their duties and obligations under the statute and the terms and conditions of this confidentiality agreement with the CCR; (c) any such questions or concerns have been resolved to their satisfaction; and (d) on the basis of the foregoing review and discussions, they are prepared to receive and use CCR data in conformity with section 103885 and the terms and conditions of this confidentiality agreement.

3. Recipient Institution and Principal Investigator agree to comply with the requirements of California Health and Safety Code section 103885, any and all other federal and state laws or regulations relating to confidentiality, security, use, access, and disclosure of CCR data, and the CCR Data Access and Disclosure Policies.

4. Recipient Institution and Principal Investigator represent and warrant that the CCR data they have requested is necessary for the above-referenced proposed use. If Recipient Institution or Principal Investigator receives CCR data that are not necessary for the above-referenced proposed use, they will immediately notify CCR and destroy the unneeded CCR data.

5. Recipient Institution and Principal Investigator agree to use the requested CCR data in strict conformity with the proposed use set forth above. Recipient Institution and Principal Investigator agree not to use the CCR data for any other purpose, or for any purpose other than determining the sources of cancer and evaluating measures designed to eliminate, alleviate, or ameliorate their effect, and they agree not to permit the CCR data to be used for any other purpose. Principal Investigator agrees to notify the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health if he or she becomes aware of errors

or omissions in the CCR data, or of patient vital statistics or address information that is more current than the CCR data provided to them under this agreement.

6. The Principal Investigator may have access to the CCR data. The Recipient Institution may grant access to the CCR data to other persons to carry out a specific assignment on behalf of the Recipient Institution, which is directly related to the use for which disclosure was granted. Persons seeking access must provide information sufficient to justify the request. The individual must sign an agreement to maintain the confidentiality of the data. Recipient Institution may use the CCR's Agreement for Access to CCR Data form (available at www.ccrcal.org) or a comparable agreement for this purpose. Recipient Institution must maintain a list with the following information: name of the person authorizing access, name, title, address, and organizational affiliation of the persons granted access, dates of access (which may cover a prospective period not to exceed one year), and the specific purpose for which the CCR data will be used. A copy of the list must be provided annually to the CCR Data Custodian. Except as provided in this paragraph, Recipient Institution agrees not to grant access to the CCR data to any person, nor shall it permit persons to whom it has granted access to authorize others to have access to the CCR data.

7. Except as expressly authorized by paragraph 9 of this Confidentiality Agreement, Recipient Institution and Principal Investigator agree not to disclose any part of the CCR data, whether or not it explicitly or implicitly identifies individuals, to any person or institution, not to copy or reproduce the CCR data in whole or in part (except as an institutional program of backup for disaster recovery or as a necessary condition of the research project), in any format or medium, and not to permit others to disclose or reproduce the CCR data. If Recipient Institution has a legitimate justification for sharing CCR data with another institution, e.g. as part of a collaborative research project, the Recipient Institution must obtain approval for this re-disclosure of the CCR data from the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.

8. Recipient Institution and Principal Investigator agree to destroy all files, documents or other records containing CCR data in their custody at the earliest opportunity consistent with the conduct of the proposed use unless there is a health or research justification for retention or retention is required by law. Notwithstanding the foregoing, Recipient Institution and Principal Investigator agree to destroy all files, documents or other records containing CCR data in their custody no later than three years after the date of receipt unless the CCR Data Custodian, in its sole discretion, extends the deadline for destruction by written notice to Recipient Institution and Principal Investigator. Destruction means physical destruction of files, documents or other records, and de-identification shall not be considered destruction. Immediately following the destruction of CCR data, Recipient Institution agree to provide the CCR Data Custodian with a written declaration, executed by an authorized representative of Recipient Institution, stating that the CCR data have been destroyed.

9. Recipient Institution and Principal Investigator may include aggregate data, conclusions drawn from studying CCR data, and case counts derived from CCR data such as incidence and mortality counts (provided that such case counts do not

in any way identify individual cases or sources of information) in professional journals, public reports, presentations, press releases and other publications. A copy shall be provided to the CCR Data Custodian and all publications shall contain the acknowledgement and disclaimer set forth in section VI.4. of the CCR Data Access and Disclosure Policies, and a copy shall be provided to the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.

10. Recipient Institution and Principal Investigator shall not grant access to, disclose, admit, produce or otherwise make available any part of the CCR data in any civil, criminal, administrative, or other tribunal or court proceeding, whether voluntarily or under compulsion. Recipient Institution and Principal Investigator shall immediately notify the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health by telephone and fax of the receipt of any subpoena, discovery request, court order, search warrant or other form of compulsory legal process or threat of compulsory legal process in which CCR data and/or documents, data files or other materials containing CCR data are sought to be produced or examined. Recipient Institution shall immediately take all necessary legal action to oppose and resist any such compulsory legal process, e.g. file a motion to quash or written objections to a subpoena, or file written objections to a discovery request and opposition to a motion to compel.

11. If the proposed use is for research, Recipient Institution and Principal Investigator represent that they have obtained approval for the proposed use from the Recipient Institution's committee for the protection of human subjects established in accordance with part 46 (commencing with section 46.101) of title 45 of the Code of Federal Regulations, and that they will carry out the proposed use in accordance with such approval, except that the terms and conditions of this confidentiality agreement shall take precedence. Principal Investigator agrees to provide documentation of initial IRB approval and any renewals. If the proposed research involves patient contact based on information received from CCR, the Recipient Institution and Principal Investigator agree to follow the special requirements required by CCR for patient contact studies including approval for the proposed use from the California Committee for Protection of Human Subjects (Section V. 6. c. Policies and Procedures).

12. Recipient Institution represents that it has policies and procedures in effect consistent with the California Information Practices Act (California Civil Code Section 1798.24 and California Welfare and Institutions Code Section 10850) to maintain the security of the CCR data in its custody, including preventing unauthorized access, and further represents that it will maintain and enforce such policies and procedures at all times during which Recipient Institution has custody of CCR data.

13. Recipient Institution represents that it has policies and procedures in effect to implement and enforce its duties and obligations under this confidentiality agreement, and further represents that it will maintain and enforce such policies and procedures at all times during which it has custody of CCR data.

14. If Recipient Institution or Principal Investigator become aware of or reasonably suspect that any provision of this agreement has been violated, or that any circumstances exist which would prevent them from complying with their obligations under this agreement, they agree to immediately notify the CCR and take immediate steps to rectify the problem and prevent any recurrence.

15. This agreement creates a non-transferable limited license for Recipient Institution and Principal Investigator to use selected CCR data provided to them. Neither Recipient Institution nor Principal Investigator shall acquire any ownership, title or other interest in any CCR data or any copy of CCR data provided to them.

16. Recipient Institution agrees to indemnify, defend and hold harmless the State of California and the CCR Data Custodian and their respective agencies, officers, directors, employees and agents from and against any and all claims, losses, damages, costs, expenses or other liability, including attorney fees and expenses, arising out of or related directly or indirectly to Recipient Institution and Principal Investigator's receipt of CCR data.

17. The CCR Data Custodian reserves the right to terminate Recipient Institution and Principal Investigator's custody of CCR data by written notice at any time without cause. Upon receipt of such notice, Recipient Institution shall immediately and permanently destroy all copies of CCR data in its custody.

18. Recipient Institution and Principal Investigator acknowledge that if they fail to comply with any of their obligations under this confidentiality agreement, the CCR Data Custodian and the State of California will suffer immediate, irreparable harm for which monetary damages will not be adequate. Recipient Institution and Principal Investigator agree that, in addition to any other remedies provided at law or in equity, the CCR Data Custodian and/or the State of California shall be entitled to injunctive relief to enforce the provisions of this agreement.

19. This is the entire agreement between the parties. It supersedes all prior oral or written agreements or understandings and it may be amended only in writing. This agreement, and the rights created hereunder, are individual and not assignable or otherwise transferable by Recipient Institution or Principal Investigator. This agreement is entered into for the benefit of the State of California, which shall have the right to enforce this agreement. This agreement and any dispute arising under this agreement shall be governed by the laws of the State of California. This agreement and the representations and covenants contained herein shall survive the expiration or termination of Recipient Institution and/or Principal Investigator's right to custody of CCR data. Any dispute that arises under or relates to this agreement shall be resolved in the State of California, Superior Court for the county in which the CCR Data custodian is located or, at the option of the State of California, Sacramento County Superior Court. In any litigation or other proceeding by which one party seeks to enforce its rights under this agreement or seeks a declaration of any rights or obligations under this agreement, the prevailing party shall be awarded reasonable attorney fees, together with any costs and expenses, to resolve the dispute and to enforce the final judgment.

20. Notwithstanding any other provision of this agreement, the CCR Data Custodian shall have no obligation to provide CCR data to Recipient Institution and Principal Investigator unless and until this agreement is approved by the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.

For Recipient Institution:

I have read the foregoing agreement. I have the authority to execute this confidentiality agreement on behalf of the Recipient Institution. By signing below I make the agreements, and representations contained therein on behalf of the Recipient Institution. I understand that these are material representations of fact upon which reliance was placed when this transaction was entered into.

Signature _____ Dated 11/10/2009

Eliseo J Perez-Stable, MD Chief Division of General Internal Med, UCL, Professor
Printed Name and Title

Principal Investigator:

I have read the foregoing agreement. By signing below I make the agreements and representations contained therein. I understand that these material representations of fact upon which reliance was placed when this transaction was entered into.

Signature _____ Dated 11/04/09

Celia Kaplan, Associate Professor.
Printed Name and Title

APPROVAL BY CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, CANCER SURVEILLANCE AND RESEARCH BRANCH:

Signature _____ Dated 3/1/10

Kurt Snipes, Chief CSRB
Printed Name and Title

RDC
2/24/2010

State of California—Health and Human Services Agency
California Department of Public Health

MARK B HORTON, MD, MSPH
Director

ARNOLD SCHWARZENEGGER
Governor

February 11, 2010

Kari Fish
Northern California Cancer Center
2201 Walnut Ave., Suite 300
Freemont, CA 94538

Dear Ms. Fish:

Please find enclosed a copy of a signed approved agreement of disclosure of CCR data for Dr. Celia Kaplan's study with Region 1/8 of the CCR entitled "Minorities and Clinical Trials: Patients, Physicians, Clinical Trail Characteristics and their Environment."

Sincerely,

Kurt P. Snipes, M.S., Ph.D., Chief
Cancer Surveillance and Research Branch

cc: Ann Brunson

Enclosure

Appendix 3: Confidentiality Agreement for Disclosure of CCR Data

The California Cancer Registry is a repository of cancer incidence data collected by the California Department of Public Health and regional cancer registries throughout the state of California from cancer reporting facilities and health-care providers under the authority of California Health and Safety Code section 103885. CCR data files contain medical and other personal information about identified individuals. By law, CCR data are confidential, and cannot be disclosed except in accordance with strict safeguards.

The University of California at San Francisco has applied to The Northern California Cancer Center for a copy of certain specified CCR data to be disclosed to Celia Kaplan, DrPH for the following proposed use: Study entitled "Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and their Environment".

In consideration for the CCR Data Custodian's disclosure of CCR data to Principal Investigator, Recipient Institution and Principal Investigator represent, warrant, and agree as follows:

1. For the purposes of this Confidentiality Agreement:

   "Recipient Institution" means the unit of government, institution, agency, the corporation, or other entity that has requested CCR data, any other unit of government, institution, agency, corporation or other entity that owns or controls the recipient institution or of which the recipient institution is a constituent part, and the directors, officers, employees, consultants, volunteers, students, contractors, agents and associates of the recipient institution.

   "Principal Investigator" means the individual that the recipient institution designated in its request to receive CCR data from the CCR, and who is principally responsible for undertaking the proposed use.

   "CCR data" means all information relating to cases of cancer collected at any time by the California Department of Public Health, a regional cancer registry designated by the Department or any other individual or institution under the authority of California Health and Safety Code Section 103885 and predecessor statutes, whether or not such information identifies an individual or could be used to identify an individual. CCR data also means all documents, files or other records, regardless of format or medium, containing CCR data (whether alone or in combination with other data).

   "Access to data" means the granting of the right to examine data.

   "Disclosure of data" means the granting of the right to examine data and the right to create or retain a copy.

   "Research" has the same definition as 45 CFR Section 46.102(d).

   "Aggregate data" means statistical information derived from CCR data that does not include any individual item of data that represents a person, whether

identified, identifiable or anonymous, and from which no information about an identifiable or anonymous person can be obtained in any manner.

"Reports and statistical information" means reports, articles, special analyses, studies, and other publications and communications that contain aggregate CCR data.

"Sources of information" means hospitals and other facilities or agencies providing diagnostic or treatment services to patients with cancer, and physicians, surgeons, dentists, podiatrists, and all other health care practitioners diagnosing or providing treatment for cancer patients, that have provided information contained in CCR data files.

2. California Health and Safety Code Section 103885 contains various provisions relating to use, access, disclosure, and publication of CCR data. These provisions may be different from the laws, regulations or policies applicable to other data used by Recipient Institution and Principal Investigator. Recipient Institution and Principal Investigator represent and warrant that: (a) they have reviewed section 103885, the California Department of Public Health, Cancer Surveillance and Research Branch, "Policies and Procedures for Access to and Disclosure of Confidential Data from the California Cancer Registry" (www.ccrcal.org) (hereinafter "CCR Data Access and Disclosure Policies"), and the terms and conditions of this confidentiality agreement; (b) they have had a full opportunity to discuss any questions or concerns they may have regarding the interpretation of section 103885 and their duties and obligations under the statute and the terms and conditions of this confidentiality agreement with the CCR; (c) any such questions or concerns have been resolved to their satisfaction; and (d) on the basis of the foregoing review and discussions, they are prepared to receive and use CCR data in conformity with section 103885 and the terms and conditions of this confidentiality agreement.

3. Recipient Institution and Principal Investigator agree to comply with the requirements of California Health and Safety Code section 103885, any and all other federal and state laws or regulations relating to confidentiality, security, use, access, and disclosure of CCR data, and the CCR Data Access and Disclosure Policies.

4. Recipient Institution and Principal Investigator represent and warrant that the CCR data they have requested is necessary for the above-referenced proposed use. If Recipient Institution or Principal Investigator receives CCR data that are not necessary for the above-referenced proposed use, they will immediately notify CCR and destroy the unneeded CCR data.

5. Recipient Institution and Principal Investigator agree to use the requested CCR data in strict conformity with the proposed use set forth above. Recipient Institution and Principal Investigator agree not to use the CCR data for any other purpose, or for any purpose other than determining the sources of cancer and evaluating measures designed to eliminate, alleviate, or ameliorate their effect, and they agree not to permit the CCR data to be used for any other purpose. Principal Investigator agrees to notify the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health if he or she becomes aware of errors

or omissions in the CCR data, or of patient vital statistics or address information that is more current than the CCR data provided to them under this agreement.

6. The Principal Investigator may have access to the CCR data. The Recipient Institution may grant access to the CCR data to other persons to carry out a specific assignment on behalf of the Recipient Institution, which is directly related to the use for which disclosure was granted. Persons seeking access must provide information sufficient to justify the request. The individual must sign an agreement to maintain the confidentiality of the data. Recipient Institution may use the CCR's Agreement for Access to CCR Data form (available at www.ccrcal.org) or a comparable agreement for this purpose. Recipient Institution must maintain a list with the following information: name of the person authorizing access, name, title, address, and organizational affiliation of the persons granted access, dates of access (which may cover a prospective period not to exceed one year), and the specific purpose for which the CCR data will be used. A copy of the list must be provided annually to the CCR Data Custodian. Except as provided in this paragraph, Recipient Institution agrees not to grant access to the CCR data to any person, nor shall it permit persons to whom it has granted access to authorize others to have access to the CCR data.

7. Except as expressly authorized by paragraph 9 of this Confidentiality Agreement, Recipient Institution and Principal Investigator agree not to disclose any part of the CCR data, whether or not it explicitly or implicitly identifies individuals, to any person or institution, not to copy or reproduce the CCR data in whole or in part (except as an institutional program of backup for disaster recovery or as a necessary condition of the research project), in any format or medium, and not to permit others to disclose or reproduce the CCR data. If Recipient Institution has a legitimate justification for sharing CCR data with another institution, e.g. as part of a collaborative research project, the Recipient Institution must obtain approval for this re-disclosure of the CCR data from the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.

8. Recipient Institution and Principal Investigator agree to destroy all files, documents or other records containing CCR data in their custody at the earliest opportunity consistent with the conduct of the proposed use unless there is a health or research justification for retention or retention is required by law. Notwithstanding the foregoing, Recipient Institution and Principal Investigator agree to destroy all files, documents or other records containing CCR data in their custody no later than three years after the date of receipt unless the CCR Data Custodian, in its sole discretion, extends the deadline for destruction by written notice to Recipient Institution and Principal Investigator. Destruction means physical destruction of files, documents or other records, and de-identification shall not be considered destruction. Immediately following the destruction of CCR data, Recipient Institution agree to provide the CCR Data Custodian with a written declaration, executed by an authorized representative of Recipient Institution, stating that the CCR data have been destroyed.

9. Recipient Institution and Principal Investigator may include aggregate data, conclusions drawn from studying CCR data, and case counts derived from CCR data such as incidence and mortality counts (provided that such case counts do not

in any way identify individual cases or sources of information) in professional journals, public reports, presentations, press releases and other publications. A copy shall be provided to the CCR Data Custodian and all publications shall contain the acknowledgement and disclaimer set forth in section VI.4. of the CCR Data Access and Disclosure Policies, and a copy shall be provided to the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.

10. Recipient Institution and Principal Investigator shall not grant access to, disclose, admit, produce or otherwise make available any part of the CCR data in any civil, criminal, administrative, or other tribunal or court proceeding, whether voluntarily or under compulsion. Recipient Institution and Principal Investigator shall immediately notify the CCR Data Custodian and the Chief, Cancer Surveillance and Research Branch, California Department of Public Health by telephone and fax of the receipt of any subpoena, discovery request, court order, search warrant or other form of compulsory legal process or threat of compulsory legal process in which CCR data and/or documents, data files or other materials containing CCR data are sought to be produced or examined. Recipient Institution shall immediately take all necessary legal action to oppose and resist any such compulsory legal process, e.g. file a motion to quash or written objections to a subpoena, or file written objections to a discovery request and opposition to a motion to compel.

11. If the proposed use is for research, Recipient Institution and Principal Investigator represent that they have obtained approval for the proposed use from the Recipient Institution's committee for the protection of human subjects established in accordance with part 46 (commencing with section 46.101) of title 45 of the Code of Federal Regulations, and that they will carry out the proposed use in accordance with such approval, except that the terms and conditions of this confidentiality agreement shall take precedence. Principal Investigator agrees to provide documentation of initial IRB approval and any renewals. If the proposed research involves patient contact based on information received from CCR, the Recipient Institution and Principal Investigator agree to follow the special requirements required by CCR for patient contact studies including approval for the proposed use from the California Committee for Protection of Human Subjects (Section V. 6. c. Policies and Procedures).

12. Recipient Institution represents that it has policies and procedures in effect consistent with the California Information Practices Act (California Civil Code Section 1798.24 and California Welfare and Institutions Code Section 10850) to maintain the security of the CCR data in its custody, including preventing unauthorized access, and further represents that it will maintain and enforce such policies and procedures at all times during which Recipient Institution has custody of CCR data.

13. Recipient Institution represents that it has policies and procedures in effect to implement and enforce its duties and obligations under this confidentiality agreement, and further represents that it will maintain and enforce such policies and procedures at all times during which it has custody of CCR data.

14. If Recipient Institution or Principal Investigator become aware of or reasonably suspect that any provision of this agreement has been violated, or that any circumstances exist which would prevent them from complying with their obligations under this agreement, they agree to immediately notify the CCR and take immediate steps to rectify the problem and prevent any recurrence.

15. This agreement creates a non-transferable limited license for Recipient Institution and Principal Investigator to use selected CCR data provided to them. Neither Recipient Institution nor Principal Investigator shall acquire any ownership, title or other interest in any CCR data or any copy of CCR data provided to them.

16. Recipient Institution agrees to indemnify, defend and hold harmless the State of California and the CCR Data Custodian and their respective agencies, officers, directors, employees and agents from and against any and all claims, losses, damages, costs, expenses or other liability, including attorney fees and expenses, arising out of or related directly or indirectly to Recipient Institution and Principal Investigator's receipt of CCR data.

17. The CCR Data Custodian reserves the right to terminate Recipient Institution and Principal Investigator's custody of CCR data by written notice at any time without cause. Upon receipt of such notice, Recipient Institution shall immediately and permanently destroy all copies of CCR data in its custody.

18. Recipient Institution and Principal Investigator acknowledge that if they fail to comply with any of their obligations under this confidentiality agreement, the CCR Data Custodian and the State of California will suffer immediate, irreparable harm for which monetary damages will not be adequate. Recipient Institution and Principal Investigator agree that, in addition to any other remedies provided at law or in equity, the CCR Data Custodian and/or the State of California shall be entitled to injunctive relief to enforce the provisions of this agreement.

19. This is the entire agreement between the parties. It supersedes all prior oral or written agreements or understandings and it may be amended only in writing. This agreement, and the rights created hereunder, are individual and not assignable or otherwise transferable by Recipient Institution or Principal Investigator. This agreement is entered into for the benefit of the State of California, which shall have the right to enforce this agreement. This agreement and any dispute arising under this agreement shall be governed by the laws of the State of California. This agreement and the representations and covenants contained herein shall survive the expiration or termination of Recipient Institution and/or Principal Investigator's right to custody of CCR data. Any dispute that arises under or relates to this agreement shall be resolved in the State of California, Superior Court for the county in which the CCR Data custodian is located or, at the option of the State of California, Sacramento County Superior Court. In any litigation or other proceeding by which one party seeks to enforce its rights under this agreement or seeks a declaration of any rights or obligations under this agreement, the prevailing party shall be awarded reasonable attorney fees, together with any costs and expenses, to resolve the dispute and to enforce the final judgment.

20. Notwithstanding any other provision of this agreement, the CCR Data Custodian shall have no obligation to provide CCR data to Recipient Institution and Principal Investigator unless and until this agreement is approved by the Chief, Cancer Surveillance and Research Branch, California Department of Public Health.

For Recipient Institution:

I have read the foregoing agreement. I have the authority to execute this confidentiality agreement on behalf of the Recipient Institution. By signing below I make the agreements, and representations contained therein on behalf of the Recipient Institution. I understand that these are material representations of fact upon which reliance was placed when this transaction was entered into.

Elisa J Perez-Stable MD 11/10/2009

Signature Dated

Elisa J Perez-Stable, MD Chief Division of General Internal Med, UCSF, Professor

Printed Name and Title

Principal Investigator:

I have read the foregoing agreement. By signing below I make the agreements and representations contained therein. I understand that these material representations of fact upon which reliance was placed when this transaction was entered into.

Celia Kaplan 11/04/09

Signature Dated

Celia Kaplan, Associate Processor.

Printed Name and Title

APPROVAL BY CALIFORNIA DEPARTMENT OF PUBLIC HEALTH, CANCER SURVEILLANCE AND RESEARCH BRANCH:

Kurt P Snipes 2/11/10

Signature Dated

Chief, CSRB Kurt Snipes

Printed Name and Title

RDC
2/10/2010

APPENDIX 5: Survey Instruments

Research Team Member (RTM) Survey

Patient Interview Survey

Physician Survey

OFFICE USE ONLY

RTM ID: _____ Site ID: _____ Date: _____/_____/_____ Initials: _____

PROSTATE CANCER RESEARCH TEAM MEMBER SURVEY

Thank you for taking the time to complete our survey about participation in prostate cancer trials. This study is funded by the Prostate Cancer Research Program as part of the Department of Defense Congressionally Directed Medical Research Program. It should take about 10 minutes to complete. Your experiences and insights will help us better understand the issues patients face when considering participation in trials.

Your answers will be kept completely confidential. Your name and the name of your organization will never be used in publications or written data results. Information that can identify you and your organization will not be shared with any third party and will be stored separately from your responses. Your participation in the survey is voluntary and you may discontinue participation at any time without penalty.

1. What is your gender? Female ☐1 Male ☐2

2. Where were you born? United States ☐1 Another country ☐2 → *Please specify*: _____

3. What is the highest educational level you have attained? *Please choose only one.*

High school, secondary school, GED or equivalent	☐1
Some college, trade school, vocational school or Associate's degree	☐2
Bachelor's degree	☐3
Graduate school	☐4

4. Do you have a nursing degree? No ☐0 Yes ☐1 → 5. Are you a Registered Nurse? No ☐0 Yes ☐1

6. Which of the following departments do you **primarily** work with? *Please choose only one.*

Urology	☐1
Medical Oncology/Hematology Oncology	☐2
Radiation Oncology	☐3
Primary Care	☐4
Other department	☐5 → *Please specify:* _____

7. How long have you been involved in research? _____Years _____Months

8. What is your job title?_____

9. Which of the following describe your duties **related to prostate cancer trials** at your organization?

a.	Lead a research team as PI or Co-Investigator ☐	f.	Manage research data ☐
b.	Direct/Lead/Manage a clinical research program ☐	g.	Conduct clinical tests or procedures on patients ☐
c.	Coordinate the day-to-day non-clinical research operations ☐	h.	Maintain regulatory documents ☐
d.	Enroll participants ☐	i.	General office/admin duties ☐
e.	Coordinate and schedule participant visits ☐	j.	Other duties ☐

↳ *Specify:* _____

_____

_____

10. In the past year, what proportion of the **prostate cancer patients** treated at your organization participated in **prostate cancer trials**? *Please give your best estimate.*

All	Almost All	Some	Almost None	None
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. In the past year, approximately what percent of your **prostate cancer trial participants**…? *Give your best estimate.*

a. were uninsured? _____%
b. were covered by Medi-Cal / Medicaid? %
c. needed a language interpreter to receive services? _____%

12. In the past year, what percent of your **prostate cancer trial participants** belonged to the following racial/ethnic groups? *Please give your best estimate.*

a. Black/African American _____%
b. Asian or Pacific Islander _____%
c. Hispanic/Latino _____%

13. What is the ethnic composition of your **prostate cancer trial research team** (including yourself, investigators, nurses, coordinators, and administrators)? *Please give your best estimate.*

a. Black/African American _____%
b. Asian or Pacific Islander _____%
c. Hispanic/Latino _____%

14. Does anyone on the **prostate cancer trial team** (including yourself) speak a language other than English well enough to obtain informed consent from study participants?

No ☐ 0 *Proceed to question 16*
Yes ☐ 1 → 15. Which languages do they speak? *Mark all that apply.*

a. Spanish ☐
b. Chinese ☐
c. Vietnamese ☐
d. Tagalog ☐
e. Other language(s) ☐

↳ *Please specify:* _____

_____

16. In the past year, how often did your organization offer the following types of language interpretation to **prostate cancer patients** at the time of **enrollment** in a cancer trial?

	Always	Sometimes	Never
a. **Non-professional** interpretation by bilingual staff	☐ 1	☐ 2	☐ 3
b. Professional language interpretation **onsite**	☐ 1	☐ 2	☐ 3
c. Professional language interpretation **by telephone**	☐ 1	☐ 2	☐ 3
d. Professional language interpretation **by internet/video**	☐ 1	☐ 2	☐ 3
e. Other types, *please specify:* _____	☐ 1	☐ 2	☐ 3

17. For which of the following languages does your organization provide **professional** (onsite, by phone, or by video) interpreter services for **prostate cancer trial participants**? *Please mark all that apply.*

a. All Languages (e.g. AT&T Language Line) ☐
b. Spanish ☐
c. Chinese ☐
d. Vietnamese ☐
e. Tagalog ☐
f. Other language(s) ☐ → *Please specify:* _____

_____

18. Which of the following printed materials are available to your **prostate cancer trial participants**?

a. Consent Forms ☐
b. "Short Form" Consent Forms ☐
c. Experimental Subjects' Bill of Rights ☐
d. Summaries of trials ☐
e. Frequently asked questions (FAQ) sheet about the studies ☐
f. Directions to study site ☐
g. Appointment reminder cards ☐
h. Study fliers or posters ☐

19. Which of the following printed materials are available to your **prostate cancer trial participants** in a language **other than English**?

a. Consent Forms ☐
b. "Short Form" Consent Forms ☐
c. Experimental Subjects' Bill of Rights ☐
d. Summaries of trials ☐
e. Frequently asked questions (FAQ) sheet about the studies ☐
f. Directions to study site ☐
g. Appointment reminder cards ☐
h. Study fliers or posters ☐

20. In the past year, which of the following methods has your organization used to recruit participants to **prostate cancer trials**? *Please mark all that apply.*

a. Recruitment videos or CDs ☐
b. Recruitment advertisements in local newspapers ☐
c. A dedicated phone line to receive patient inquiries about the cancer trials ☐
d. Presentations about the trials to community groups and churches ☐
e. Presentations to health providers **within your organization** *including Tumor Boards and Conferences* ☐
f. Presentations to health providers **outside your organization** ☐
g. Distributing trial information at community health fairs or cancer awareness days ☐
h. Posting the trials on your hospital/organization's website ☐
i. Other activities, *please specify:*_____ ☐

21. In the past year, which of the following incentives has your organization provided to your **prostate cancer trial participants**? *If no incentives provided, please mark 'Not provided'.*

		For <u>all</u> participants	For <u>some</u> participants	Not provided
a.	Complimentary or valet parking	☐1	☐2	☐3
b.	Help with transportation (e.g. bus tickets or taxi vouchers)	☐1	☐2	☐3
c.	Cash or gift cards/certificates	☐1	☐2	☐3
d.	Complimentary food or beverages	☐1	☐2	☐3
e.	Sponsor-provided gifts (e.g., mugs, pencils, t-shirts)	☐1	☐2	☐3
f.	Other incentive(s), *please specify:* _____ _____	☐1	☐2	☐3

22. Below is a list of factors that may be barriers for **patients** to participate in **prostate cancer trials**. Please indicate if you think each factor is a major barrier, a moderate barrier, a minor barrier, or not a **barrier for patients**.

	Patients…	**Major** Barrier	**Moderate** Barrier	**Minor** Barrier	**Not** a Barrier
a.	are concerned that the risks outweigh the benefits.	☐1	☐2	☐3	☐4
b.	are concerned that the trials cannot accommodate non-English speakers.	☐1	☐2	☐3	☐4
c.	don't understand what clinical trials are.	☐1	☐2	☐3	☐4
d.	lack adequate insurance coverage.	☐1	☐2	☐3	☐4
e.	don't meet the eligibility or study entry criteria.	☐1	☐2	☐3	☐4
f.	lack transportation.	☐1	☐2	☐3	☐4
g.	are reluctant to complete paperwork.	☐1	☐2	☐3	☐4
h.	are unable to take time from work, family, or other duties.	☐1	☐2	☐3	☐4

23. Below is a list of factors that may be barriers for **physicians** to refer or enroll their patients for **prostate cancer trials**. Please indicate if you think each factor is a major barrier, a moderate barrier, a minor barrier, or not a **barrier for physicians**.

	Physicians…	**Major** Barrier	**Moderate** Barrier	**Minor** Barrier	**Not** a Barrier
a.	are concerned that the trial treatment will be inferior to standard treatments.	☐1	☐2	☐3	☐4
b.	are concerned that patients referred to trials will not return to their practice.	☐1	☐2	☐3	☐4
c.	are concerned about the time and effort required to explain trials to the patient.	☐1	☐2	☐3	☐4
d.	are concerned about inadequate reimbursement from research sponsors.	☐1	☐2	☐3	☐4
e.	don't have adequate time dedicated for research.	☐1	☐2	☐3	☐4
f.	don't have adequate information about the trials.	☐1	☐2	☐3	☐4
g.	are concerned that patients will not adhere with the study protocol.	☐1	☐2	☐3	☐4

Thank you for completing the survey! Please email, fax, or mail this survey to:

Maya Yoshida - Research Coordinator
Mail: UCSFBox 0856 / San Francisco Ca 94143-0856
Fax: 415-502-8291
Email: myoshida@medicine.ucsf.edu
Phone: 1-888-663-6661

Email Version: March 2010

DOD PROSTATE: PATIENT INTERVIEW

PATIENT ID	INTERVIEWER	TODAY'S DATE	LANGUAGE
_____ - _____		/ /	

Hello, my name is [_____]. I'm calling from the University of California, San Francisco. May I speak with [_____], please?

RESPONDENT ON PHONE	1	CONTINUE
RESPONDENT NOT AVAILABLE	2	When would be a good time to call back? _____ Thanks for your time. Have a nice day/evening. END CALL.
RESPONDENT NOT AT THIS NUMBER	3	Do you know how I can reach him? _____ Thanks for your time. Have a nice day/afternoon/evening. END CALL.

IF APPLICABLE: Which language would you prefer to speak in?

ENGLISH	1	READ NEXT SECTION IN ENGLISH
SPANISH	2	READ NEXT SECTION IN SPANISH
CANTONESE	3	READ NEXT SECTION IN CANTONESE
TAGALOG	4	READ NEXT SECTION IN TAGALOG
OTHER	5	CONTINUE

IF OTHER LANGUAGE: Would you feel comfortable answering questions about your health in one of the following four languages?

	YES	NO	
English	1	2	CONTINUE IN ENGLISH
Spanish	1	2	CONTINUE IN SPANISH
Cantonese	1	2	CONTINUE IN CANTONESE
Tagalog	1	2	CONTINUE IN TAGALOG
NONE /OTHER	1	2	I'm sorry; we can only do this survey in English, Spanish, Cantonese, or Tagalog. Thank you for your time and have a nice day/afternoon/evening. END CALL.

I'm calling to follow up on a letter that was sent to you recently. This letter described a research study that Dr. Kaplan is conducting at the UCSF Department of Medicine. In this study, we hope to learn about why people decide to participate or not participate in prostate cancer research studies. This project is funded by the Prostate Cancer Research Program which is one of the Department of Defense Congressionally Directed Medical Research Programs. We are calling you because you were selected from the California Cancer Registry as someone who was diagnosed with prostate cancer within the past three years. We are asking you to participate in a 20 to 30-minute phone interview. We will ask questions about you and what you think about health research studies. We will use this information to help increase participation in prostate cancer research studies. After the interview, we will send you a $10.00 gift card as a thank you for your time and participation.

Would you like to participate in this study?

NO

That's fine. Thanks so much for your time and have a nice day/afternoon/evening. END CALL.

MAYBE—[IF CAN'T DECIDE / WANTS MORE INFO]

OFFER TO RESEND LETTER & INFO SHEET OR PROVIDE CELIA'S INFORMATION.

SCHEDULE A TIME TO CALL BACK: _____

DR. CELIA KAPLAN
(415) 502-5601
CELIA.KAPLAN@UCSF.EDU
END CALL.

UCSF
BOX 0856
SAN FRANCISCO, CA 94143

YES—INITIAL BELOW AND CONTINUE

That's great, thank you! Is this a good time to do the interview?

YES	1	CONTINUE
NO, LATER	2	When would be a good time to call back? _____ thanks for your time, and I'll be calling you on _____. Have a nice day/afternoon/evening. END CALL.

[CONSENT]

Just to let you know, your name, answers, and study records will be kept confidential. However, representatives of the committees on Human Research at UCSF and the funding agency are eligible to review your research records as a part of their responsibility to protect human volunteers in research.

Your participation is entirely voluntary and will not affect your health care or health insurance in any way. You can refuse to participate without consequences. If you do decide to participate, you are free to skip any questions that you do not feel comfortable answering, and you may stop the interview at any time. Do you have any questions?

Shall we begin?

INITIALS		DATE	

LANGUAGE & HEALTH

First, I am going to ask you a few questions about yourself.

1. Overall, how would you rate your health? Would you say it is….?

Excellent	1
Very good	2
Good	3
Fair	4
Poor	5
DK	77
REF	99

2. Is English your first language?

YES	1	GO TO # **7**
NO	0	CONTINUE
DK	77	
REF	99	

3. What is your first language?

SPANISH	1	CONTINUE
CANTONESE	2	CONTINUE
TAGALOG	3	CONTINUE
OTHER	4	* INELIGIBLE
3a. OTHER SPECIFY_____		

4. How well do you speak English? Would you say…?

Very Well	1	
Well	2	
So, so	3	**PARTICIPANT IS LEP**
Poorly	4	**PARTICIPANT IS LEP**
Not at all	5	**PARTICIPANT IS LEP**
DK	77	
REF	99	

5. In general, in what language do you prefer to receive your medical care?

ENGLISH	1
SPANISH	2
CANTONESE	3
TAGALOG	4
BOTH EQUALLY – ENGLISH/SPANISH	5
BOTH EQUALLY – ENGLISH/CANTONESE	6
BOTH EQUALLY – ENGLISH/TAGALOG	7
OTHER	8
5a. OTHER SPECIFY:_____	

6. [LANGUAGE ACCULTURATION] ___' = OTHER LANGUAGE INDICATED IN QUESTION 3

	Would you say…?	Only (___)	(___) better than English	Both equally	English better than (___)	Only English	DK	REF
a.	In general, what language do you read and speak?	1	2	3	4	5	77	99
	Would you say…?	**Only (___)**	**More (___) than English**	**Both equally**	**More English than (___)**	**Only English**	**DK**	**REF**
b.	What language do you usually speak at home?	1	2	3	4	5	77	99
c.	In which language do you usually think?	1	2	3	4	5	77	99
d.	What language do you usually speak with your friends?	1	2	3	4	5	77	99

7. These next questions are about how you obtain medical information.

	Would you say…?	Always	Often	Sometimes	Rarely	Never	DK	REF
a.	How often do you have someone like a family member, friend, hospital worker or caregiver, help you read hospital materials?	1	2	3	4	5	77	99
b.	How often are you comfortable with filling out medical forms by yourself?	1	2	3	4	5	77	99
c.	How often do you have problems learning about your medical condition because of difficulty understanding the written information?	1	2	3	4	5	77	99

DIAGNOSIS & TREATMENT

Now I would like to learn about your prostate cancer diagnosis and treatment.

8. In what month and year was your prostate cancer first diagnosed?

MONTH	____
YEAR	____ ____
DK	77
REF	99

9. Now please think about the tests and exams you had which led to the biopsy that diagnosed your prostate cancer. Please let me know if you need me to explain any words that you are unsure of.

		YES	NO	DK	REF
a.	Did you have a PSA test that led to the biopsy? [PROBE: A PSA test is a blood test to diagnose prostate cancer.]	1	0	77	99
b.	Did you have a Digital Rectal Exam (DRE) that led to the biopsy? [PROBE: This is when the doctor checks the surface of the prostate with a finger through the rectum.]	1	0	77	99
c.	Was your prostate cancer diagnosed some other way?	1	0	77	99
	c1. IF YES: How was it diagnosed? OTHER SPECIFY:_____				

10. Which of the following treatments did you receive for your prostate cancer? Again, please let me know if you need me to explain any words that you are unsure of. Did you receive…?

		YES	NO	DK	REF
a.	**Watchful waiting?** [PROBE: This is when your doctor regularly monitors your condition without treatment, until symptoms or blood test results change.]	1	0	77	99
b.	**Prostate Surgery?** [PROBE: This is when a doctor removes the prostate in an operation.]	1	0	77	99
c.	**Internal Radiation Therapy or Brachytherapy?** [PROBE: This is when a doctor places radioactive ‗seeds' or other devices near the tumor to release radiation to kill the prostate cancer cells.]	1	0	77	99
d.	**External Radiation therapy?** [PROBE: This is when a patient receives external radiation to kill the prostate cancer cells.]	1	0	77	99
e.	**Hormone therapy?** [PROBE: This is when a doctor uses pills or shots to decrease the production of male hormones produced in the body.]	1	0	77	99
f.	**Chemotherapy?** [PROBE: This is when a doctor uses medications, usually given through the vein, to kill prostate cancer cells over weeks or months.]	1	0	77	99
g.	**Any other treatment?**	1	0	77	99
	g1. OTHER SPECIFY: _____				

11. Now please think about how the decisions were made for your prostate cancer treatment. How often did you and your doctor work out a treatment plan together? Would you say…?

Always	1
Often	2
Sometimes	3
Rarely	4
Never	5
DK	77
REF	99

12. How often did your doctors ask if you would like to help decide your prostate cancer treatment? Would you say…?

Always	1
Often	2
Sometimes	3
Rarely	4
Never	5
DK	77
REF	99

13. Has a doctor ever told you that you had any of the following health conditions?

		YES	NO	DK	REF
a.	Heart disease	1	0	77	99
b.	High blood pressure	1	0	77	99
c.	Lung disease	1	0	77	99
d.	Diabetes	1	0	77	99
e.	Ulcer or stomach disease	1	0	77	99
f.	Kidney disease	1	0	77	99
g.	Liver disease	1	0	77	99
h.	Anemia or other blood disease	1	0	77	99
i.	Other Cancer	1	0	77	99
	i1. CANCER SPECIFY: _____				
j.	Depression	1	0	77	99
k.	Arthritis (Osteoarthritis, Rheumatoid arthritis, or degenerative arthritis,)	1	0	77	99
l.	Other health conditions	1	0	77	99
	l1. OTHER SPECIFY: _____				

Now I would like to learn about the doctors you saw for your prostate cancer. Please think about all the doctors you talked to about your diagnosis and treatment. [GO TO CALL LOG FOR PHYSICIAN'S INFORMATION.]

MUST OBTAIN AT LEAST **2 PHYSICIANS' CONTACT INFORMATION FOR THE PHYSICIAN SURVEY**

14. Our records indicate that Dr. _____ was one of your doctors who diagnosed or treated your prostate cancer? Is this correct?

YES	1	→
NO	0	GO TO #**20**
DK	77	
REF	99	

15. What is Dr. _____'s specialty?

[PROBE: **Is he/she….?**]

A urologist or surgeon	1
A medical oncologist	2
A radiation oncologist	3
A primary care doctor	4
Some other specialty	5
15a. _____	
DK	77
REF	99

16. Did you see Dr. _____ at…?

		16a. What is the name of the place where you saw Dr._____?	16b. Where is it located? [CROSS STREET & CITY)
A Private Office	1	_____	_____ _____
A Hospital or Clinic	2	_____	_____ _____
DK	77		
REF	99		

IF 2ND PHYSCIAN IS NOT PROVIDED, GO TO #20, OTHERWISE CONTINUE

17. Our records also indicate that Dr. _____ was one of your doctors who diagnosed or treated your prostate cancer? Is this correct?

YES	1	→
NO	0	GO TO #**20**
DK	77	
REF	99	

18. What is Dr. _____'s specialty?

[PROBE: **Is he/she….?**]

A urologist or surgeon	1
A medical oncologist	2
A radiation oncologist	3
A primary care doctor	4
Some other specialty	5
18a. _____	
DK	77
REF	99

19. Did you see Dr. _____ at…?

		19a. What is the name of the place where you saw Dr. ____?	19b. Where is it located? [CROSS STREET & CITY)
A Private Office	1	_____	_____ _____
A Hospital or Clinic	2	_____	_____ _____
DK	77		
REF	99		

IF THE 2 PHYCISIANS ARE CONFIRMED, GO TO #26, OTHERWISE CONTINUE

20. [Besides Dr.(s) _____] Can you tell me the name of [a/another] doctor who diagnosed or treated your prostate cancer? (PROBE: Can you spell their name for me?)

_____	→	21. What is Dr. _____'s specialty?
DK	77	
REF	99	

[PROBE: **Was he/she….?**]	
A urologist or surgeon	1
A medical oncologist	2
A radiation oncologist	3
A primary care doctor	4
Some other specialty	5
21a. _____	
DK	77
REF	99

22. Did you see Dr. _____ at…?

		22a. What is the name of the place where you saw Dr. ____?	22b. Where is it located? [CROSS STREET & CITY)
A Private Office	1	_____	_____ _____
A Hospital or Clinic	2	_____	_____ _____
DK	77		
REF	99		

IF 2 PHYCISIANS ARE LISTED, GO TO #26, OTHERWISE CONTINUE

23. [Besides Dr.(s) _____] Can you tell me the name of [a/another] doctor who diagnosed or treated your prostate cancer? (PROBE: Can you spell their name for me?)

_____	→	24. What is Dr. _____'s specialty?
DK	77	
REF	99	

[PROBE: **Is he/she….?**]	
A urologist or surgeon	1
A medical oncologist	2
A radiation oncologist	3
A primary care doctor	4
Some other specialty	5
24a. _____	
DK	77
REF	99

25. Did you see Dr. _____ at…?

		25a. What is the name of the place where you saw Dr. ____?	25b. Where is it located? [CROSS STREET & CITY)
A Private Office	1	_____	_____ _____
A Hospital or Clinic	2	_____	_____ _____
DK	77		
REF	99		

CONTINUE TO #26

26. Which one of the doctors you mentioned helped you the most with your prostate cancer diagnosis and treatment? Was it…?

[IF THE PATIENT CANNOT DECIDE: Which doctor did you see most often during your diagnosis and treatment?]

Dr. _____ [1ST PHYSICIAN]	1
Dr. _____ [2ND PHYSICIAN]	2
OTHER PHYSICIAN	3
↳ 26a. Can you spell their name for me? _____	
DK	77
REF	99

IF PARTICIPANT MENTIONS ANOTHER PHYISICIAN

26b. **What is Dr. _____'s specialty?**

Was he/she….?	
A urologist or surgeon	1
A medical oncologist	2
A radiation oncologist	3
A primary care doctor	4
Some other specialty	5
26b1. _____	
DK	77
REF	99

26c. Did you see Dr. _____ at…?

		26c1. What is the name of the place where you saw Dr. ____?	26c2. Where is it located?
A Private Office	1	_____	_____ _____
A Hospital or Clinic	2	_____	_____ _____
DK	77		
REF	99		

GO TO #27

CLINICAL TRIAL BACKGROUND

The next questions are about health research studies you may have participated in **before** your prostate cancer diagnosis.

27. **Before** your diagnosis, have you ever participated in a health research study where…..? [PROBE: READ THE INSTRUCTIONS AGAIN WHEN YOU REACH QUESTION #27C.]

		YES	NO	DK	REF
a.	you answered questions on paper, in an interview, or in a focus group?	1	0	77	99
b.	they gathered any blood or tissue samples for research purposes?	1	0	77	99
c.	you tried a new medicine, medical treatment, or procedure for research purposes?	1	0	77	99
d.	you made any behavioral changes, like diet or exercise for research purposes?	1	0	77	99
e.	you did something else?	1	0	77	99
	e1. OTHER SPECIFY: _____				

[IF "YES" TO ANY OF THE ABOVE IN QUESTION 27]

28. How many health research studies did you participate in **before** your prostate cancer diagnosis?

___ ___	
DK	77
REF	99

29. Have you ever heard of the term **clinical trial**?

YES	1	→	[As you know,] a **clinical trial** is a specific type of study that examines a new medicine, medical treatment, or procedure in order to prevent, diagnose or treat a medical condition.
NO	0		
DK	77		
REF	99		

30. **Before** your prostate cancer diagnosis, did you ever participate in a **clinical trial**?

YES	1	IF YES →	30a. How many?	___ ___	
NO	0	GO TO # **32**		DK	77
DK	77	CONTINUE		REF	99
REF	99	GO TO # **32**			

31. What was being tested in the clinical trial(s)? Was it…?

		YES	NO	DK	REF
a.	a medicine, like a pill, injection, or drug given through an IV?	1	0	77	99
b.	a medical treatment or procedure, like a type of surgery or radiation?	1	0	77	99
c.	behavioral changes, like diet or exercise?	1	0	77	99
d.	Were they examining anything else?	1	0	77	99
	d1. OTHER SPECIFY: _____				

Now I am going to ask about health research studies you may have participated in **after** your prostate cancer diagnosis.

32. **Since** your diagnosis, aside from this study, have you ever participated in a health research study where…?

		YES	NO	DK	REF
a.	you answered questions on paper, in an interview, or in a focus group?	1	0	77	99
b.	they gather any blood or tissue samples for research purposes?	1	0	77	99
c.	you tried a new medicine, medical treatment, or procedure for research purposes?	1	0	77	99
d.	you made any behavioral changes, like diet or exercise for research purposes?	1	0	77	99
e.	you did something else?	1	0	77	99
	e1. OTHER SPECIFY: _____				

IF NO TO ALL QUESTIONS ABOVE, GO TO #34, OTHERWISE CONTINUE

33. How many health research studies did you participate in **since** your prostate cancer diagnosis?

____ ____	
DK	77
REF	99

33a. (Was this study/Were these studies) related to prostate cancer?

YES	1	IF YES →	33b. How many?	____ ____	
NO	0	GO TO #34		DK	77
DK	77			REF	99
REF	99				

33c. Of the prostate cancer research studies you participated in, what did they ask you to do? Did…?

		YES	NO	DK	REF
a.	you answered questions on paper, in an interview, or in a focus group?	1	0	77	99
b.	they gather any blood or tissue samples for research purposes?	1	0	77	99
c.	you tried a new medicine, medical treatment, or procedure for research purposes?	1	0	77	99
d.	you made any behavioral changes, like diet or exercise for research purposes?	1	0	77	99
e.	you did something else?	1	0	77	99
	e1. OTHER SPECIFY: _____				

CONTINUE

34. Thinking back to the definition I gave you about clinical trials have you ever talked with any of your doctors, nurses, or other medical staff about participating in prostate cancer clinical trials since your diagnosis?

[IF THEY DO NOT REMEMBER, PLEASE READ THE DEFINITION AGAIN: A **clinical trial** is a specific type of study that examines a new medicine, medical treatment, or procedure in order to prevent, diagnose or treat a medical condition.]

YES	1	**GO TO # 36**
NO	0	CONTINUE
DK	77	CONTINUE
REF	99	CONTINUE

[IF NO]

35. Would you have wanted to talk with your doctors, nurses, or other medical staff about prostate cancer clinical trials?

YES	1	**GO TO # 41**
NO	2	
DK	77	
REF	99	

[IF YES]

36. Who did you talk to about prostate cancer clinical trials? Was it with…?

		YES	NO	DK	REF
a.	A urologist or surgeon	1	0	77	99
b.	A radiation oncologist	1	0	77	99
c.	A medical oncologist	1	0	77	99
d.	A primary care doctor	1	0	77	99
e.	Any other doctor, nurse, or other medical staff?	1	0	77	99
	e1. If so, who? _____				

37. Who first mentioned the clinical trial; was it you or your (doctor/ nurse, or other medical staff)? [MARK ALL THAT APPLY]

PARTICIPANT	1
DOCTOR	2
NURSE	3
CLINIC STAFF	4
DK	77
REF	99

38. Did you talk about any specific prostate cancer clinical trials?

YES	1	
NO	0	→ 38a. Why not? _____ _____ **[GO TO # 41]**
DK	77	
REF	99	

39. Were you invited to participate in any prostate cancer clinical trials?

YES	1	→	39a. How many?	____ ____	
NO	2			DK	77
DK	77			REF	99
REF	99				

40. Did your doctor/ nurse/other medical staff recommend that you participate in the clinical trial?

YES	1
NO	0
DK	77
REF	99

41. Just to confirm, since your prostate cancer diagnosis, did you participate in a prostate cancer clinical trial?

YES	1	CONTINUE
NO	0	IF NO → 41a. Why not? _____ _____ **[GO TO #45]**
DK	77	**GO TO # 45**
REF	99	**GO TO # 45**

42. How many prostate cancer clinical trials did you participate in since your diagnosis?

____ ____	
DK	77
REF	99

43. What was being tested in the clinical trial(s)? Was it…?

		YES	NO	DK	REF
a.	…a medicine, like a pill, injection, or drug given through an IV?	1	0	77	99
b.	…a medical treatment or procedure, like a type of surgery or radiation?	1	0	77	99
c.	…lifestyle changes, like diet or exercise?	1	0	77	99
d.	Were they examining anything else?	1	0	77	99
	d1. OTHER SPECIFY: _____				

44. Overall, how satisfied are you with your experience in the prostate cancer clinical trial you participated in? Would you say…?

Extremely satisfied	1
Very satisfied	2
Somewhat satisfied	3
Not at all satisfied	4
DK	77
REF	99

IF PARTICIPATED IN 2nd TRIAL:	
Extremely satisfied	1
Very satisfied	2
Somewhat satisfied	3
Not at all satisfied	4
DK	77
REF	99

45. In the future, would you participate in a prostate cancer-related clinical trial if offered the opportunity? Would you say…?

Definitely Yes	1
Probably Yes	2
Probably Not	3
Definitely Not	4
DK	77
REF	99

46. If your prostate cancer were to come back or get worse, would you want to participate in a clinical trial? Would you say…?

Definitely Yes	1
Probably Yes	2
Probably Not	3
Definitely Not	4
DK	77
REF	99

47. If a family member or a close friend asked for your advice regarding participating in a clinical trial would you recommend participation? Would you say…?

Definitely Yes	1
Probably Yes	2
Probably Not	3
Definitely Not	4
DK	77
REF	99

48. If your doctor asked you to consider participating in any clinical trial, how likely would you be to participate? Would you say…?

Definitely Yes	1
Probably Yes	2
Probably Not	3
Definitely Not	4
DK	77
REF	99

49. Have you ever obtained information on clinical trials from the following sources?

		YES	NO	DK	REF
a.	the internet	1	0	77	99
b.	a doctor	1	0	77	99
c.	a nurse	1	0	77	99
d.	brochures or pamphlets from the doctor‘s office	1	0	77	99
e.	friends or family	1	0	77	99
f.	someone with cancer	1	0	77	99
g.	cancer organization, like the American Cancer Society or the National Cancer Institute	1	0	77	99
h.	a telephone health information line	1	0	77	99
i.	Other source	1	0	77	99
	i1. SPECIFY: _____				

50. The following statements are some reasons why patients do not participate in clinical trials. For each reason, let me know how much of a barrier it would be for you to participate. [PROBE: If you were asked to participate in a clinical trial, how much of a barrier would the following reasons be for you to participate?]

		Major Barrier	Moderate Barrier	Minor Barrier	Not a Barrier	DK	REF
a.	You are concerned that the risks outweigh the benefits. Would you say this is a…(for you)?	1	2	3	4	77	99
b.	You are concerned that the trials cannot accommodate people who don‘t speak English. Would you say this is a …(for you)?	1	2	3	4	77	99
~~c.~~	~~You don‘t understand what clinical trials are. Would you say this is a…(for you)?~~	~~1~~	~~2~~	~~3~~	~~4~~	~~77~~	~~99~~
d.	You lack adequate insurance coverage to participate in a clinical trial. Would you say this is a…(for you)?	1	2	3	4	77	99
e.	You lack transportation. Would you say this is a…(for you)?	1	2	3	4	77	99
f.	You are reluctant to complete paperwork. Would you say this is a…(for you)?	1	2	3	4	77	99
g.	You are unable to take time from work, family, or other duties. Would you say this is a…(for you)?	1	2	3	4	77	99

51. Now please indicate how important the following reasons would be for you to participate in a clinical trial.

		Very Important	Important	Somewhat important	Not at all important	DK	REF
a.	Having the opportunity to get a —new" medical treatment. Would you say this is…?	1	2	3	4	77	99
b.	Knowing your prostate cancer would be watched more closely. Would you say this is…?	1	2	3	4	77	99
c.	The wish to help future patients by helping to test a "new" medical treatment. Would you say this is…?	1	2	3	4	77	99

KNOWLEDGE

52. Now I am going to read you a list of statements about clinical trials. Please indicate whether you think these statements are true, false, or you are unsure.

		TRUE	FALSE	UNSURE	REF
a.	People who participate in clinical trials have the right to withdraw at any time.	1	2	3	99
b.	Participation in a clinical trial is entirely voluntary.	1	2	3	99
c.	Patients in clinical trials may have their medical information or names published.	1	2	3	99
d.	A –Consent Form" is used to describe the potential risks and benefits of entering a clinical trial.	1	2	3	99
e.	If a clinical trial is asking a very important question, doctors can force patients to participate.	1	2	3	99
f.	Patients can be placed in a clinical trial without their knowledge.	1	2	3	99
g.	The best way to find out if one treatment is better than another is to assign participants by chance to the different treatments.	1	2	3	99
h.	Patients must sign a –Consent Form" when entering a clinical trial.	1	2	3	99
i.	All clinical trials are conducted by drug companies.	1	2	3	99

ATTITUDES TOWARDS RESEARCH & PARTICIPATION

53. Now I am going to read you a list of statements regarding your opinions about clinical trials. For each statement, please let me know how much you agree, disagree, or if you remain neutral.

		Agree		Neutral	Disagree			
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	DK	REF
a.	Clinical trials are important for the development of new cancer treatments. Would you say you…?	1	2	3	4	5	77	99
b.	Clinical trials conducted by drug companies are as good as studies conducted by universities. Would you say you…?	1	2	3	4	5	77	99
c.	All cancer patients should have the opportunity to take part in clinical trials. Would you say you…?	1	2	3	4	5	77	99
d.	Clinical trials benefit researchers more than they benefit patients. Would you say you…?	1	2	3	4	5	77	99
e.	Patients in clinical trials get the latest cancer treatments. Would you say you…?	1	2	3	4	5	77	99
f.	Patients receive better care if they take part in a clinical trial. Would you say you…?	1	2	3	4	5	77	99
g.	Patients are treated as experimental objects in clinical trials. Would you say you…?	1	2	3	4	5	77	99
h.	Clinical trials require participants to undergo extra medical procedures. Would you say you…?	1	2	3	4	5	77	99

SOCIODEMOGRAPHICS

These last few questions are about yourself.

54. Can you please tell me what type of health insurance you have? For each type of insurance, please indicate which ones apply to you.

	YES	NO	DK	REF
Private insurance including HMO (e.g. Kaiser, Blue Shield, Blue Cross)	1	0	77	99
Medi-Cal / Medicaid	1	0	77	99
Medicare	1	0	77	99
Veteran's Affair (VA)	1	0	77	99
No insurance	1	0	77	99
Other	1	0	77	99
54a. OTHER SPECIFY: _____				

54b. Would you describe yourself as…?

White / Caucasian	1	
Hispanic / Latino	2	
Black / African-American	3	
Asian-American	4	GO TO #54d
Other ethnicity	5	GO TO #54c, IF THEY ARE MORE THAN ONE GROUP GO TO #54d, IF THEY ARE AN ASIAN ETHNICITY
54b1. OTHER SPECIFY:_____		
MORE THAN ONE GROUP	6	GO TO #54c
DK	77	GO TO #54c
REF	99	

54c. [IF MORE THAN ONE GROUP OR DK] With which race or ethnicity do you identify the most?*

WHITE / CAUCASIAN	1	
HISPANIC / LATINO	2	
BLACK / AFRICAN-AMERICAN	3	
ASIAN-AMERICAN	4	CONTINUE TO #54d
OTHER ETHNICITY	5	
54c1. OTHER SPECIFY:_____		
DK	77	
REF	99	

54d. [IF HE DESCRIBES HIMSELF AS ASIAN] Which of the following best describes your ethnicity?

Chinese	1
Japanese	2
Filipino	3
Vietnamese	4
Hawaiian	5
Other Pacific Islander	6
54d1. OTHER SPECIFY:_____	
Other Asian American	7
54d2. OTHER SPECIFY:_____	
DK	77
REF	99

55. In what country were you born?

U.S.	1	
OTHER COUNTRY: _____	2	→ 56. In total, how many years have you lived in the U.S.? _____ _____
DK	77	
REF	99	

57. How old are you? _____

58. What is the highest year of school you have completed?

GRADE SCHOOL		**COLLEGE/UNIVERSITY/COMMUNITY COLLEGE**	
1ST GRADE	1	1ST YEAR (FRESHMAN)	13
2ND GRADE	2	2ND YEAR (SOPHOMORE) (AA)	14
3RD GRADE	3	3RD YEAR (JUNIOR)	15
4TH GRADE	4	4TH YEAR (SENIOR) (BA/BS)	16
5TH GRADE	5	**GRADUATE OR PROFESSIONAL SCHOOL**	17
6TH GRADE	6	DK	77
7TH GRADE	7	REF	99
8TH GRADE	8		
HIGH SCHOOL OR EQUIVALENT			
9TH GRADE	9		
10TH GRADE	10		
11TH GRADE	11		
12TH GRADE (HS graduate/GED)	12		

59. Are you…?

	YES	NO	DK	REF
Working full-time	1	0	77	99
Working part-time	1	0	77	99
Retired	1	0	77	99
A student	1	0	77	99
Not working	1	0	77	99
OTHER	1	0	77	99
59a. OTHER SPECIFY: _____				

60. Are you…?

Single (never married)	1
Living with a long-term partner	2
Married	3
Legally separated or divorced	4
Widowed	5
OTHER	6
60a. OTHER SPECIFY: _____	
DK	77
REF	99

61. How many people live in your household, including yourself? By ~~h~~household", I mean people who live together <u>and</u> depend on the same incomes.

_____ _____	PEOPLE	
	DK	77
	REF	99

62. During the past year, what was your household's general income before taxes? Again, this information is completely confidential. I'll be reading you some categories to choose from. Would it be easiest for you if I read the categories per year, per month, or per week?

PER YEAR	PER MONTH	PER WEEK	
$5000 or less	$417 or less	$97 or less	1
$5001 to $10,000	$418 to $833	$98 to $192	2
$10,001 to $20,000	$834 to $1,666	$193 to $384	3
$20,001 to $40,000	$1,667 to $3,333	$385 to $769	4
$40,001 to $70,000	$3,334 to $5,833	$770 to $1,346	5
More than $70,000	More than $5,833	More than $1,346	6
DK			77
REF			99

This is the end of the survey. Before we hang up I'd like to verify with you the address of the best place for me to mail your $10 gift card as a thank you for participating.

NAME:	
STREET1:	
STREET2:	
CITY & ZIP	

I also would like to know whether you might be willing to participate in future health studies. Saying "YES" does not commit you to anything; it just means we might send you information about future studies.

YES	1
NO	0
DK	77
REF	99

Thank you again for your time and participation. It is greatly appreciated.

Patient Participation in Prostate Cancer Clinical Trials

Thank you for taking time to complete this survey about patient participation in prostate cancer clinical trials. Your privacy will be maintained in all published data and written documents resulting from the study. Participation in this survey is voluntary.

It should take less than 10 minutes to answer all of the questions.

If you have any questions regarding the study or would like to speak to the Principal Investigator Dr. Celia Kaplan, please contact her by e-mail at *celia.kaplan@ucsf.edu* or by phone at the University of California San Francisco at (415) 502-5601.

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University of California
San Francisco
Department of Medicine

Section A. Specialty and work-related time

1. In your best estimate, how many ***prostate cancer patients*** (newly diagnosed, under surveillance, or undergoing treatment) do you personally treat per month?

_____ *prostate cancer patients per month*

If you **do not treat patients with prostate cancer**, *please* **stop here** *and return the survey. Thank you.*

2. What is your primary medical specialty? *Please check* ***one*** *answer only.*

- ☐ 1 Urology
- ☐ 2 Radiation Oncology
- ☐ 3 Hematology/Oncology
- ☐ 4 Primary Care
- ☐ 5 Other _____ *please specify*

3. In your best estimate, what percentage of your work-related time do you spend in...

- a. Patient care *(e.g., seeing patients, calling consultants, reviewing lab results)* ☐☐☐ %
- b. Teaching activities ☐☐☐ %
- c. Research activities ☐☐☐ %
- d. Administrative activities *(e.g., committee & other professional activities)* ☐☐☐ %

4. What proportion of your practice is made up of prostate cancer patients? Would you say...

- ☐ 1 Less than 5%
- ☐ 2 5% to 10%
- ☐ 3 11% to 25%
- ☐ 4 26% to 50%
- ☐ 5 More than 50%

Section B. Patient and primary practice site characteristics

5. Which ***one*** of the following best describes your primary practice site? *Please check* ***one*** *answer only.*

- ☐ 1 University/medical school-based practice (not including public or VA hospitals)
- ☐ 2 Public hospital
- ☐ 3 VA hospital/clinic
- ☐ 4 Hospital (community, non-profit, for-profit)
- ☐ 5 Solo, single specialty, or multi-specialty group
- ☐ 6 Group model HMO (e.g., Kaiser Permanente)
- ☐ 7 Public/community health center
- ☐ 8 Other setting _____ *please specify*

6. In your best estimate, what percentage of your patients are insured by...

- a. Medicare (with or without supplemental insurance) ☐☐☐ %
- b. Medicaid ☐☐☐ %
- c. Private insurance or HMO (including Kaiser) ☐☐☐ %
- d. No insurance / Other public insurance ☐☐☐ %

7. In your best estimate, what percentage of your patients are...

- a. Black or African American ☐☐☐ %
- b. Asian, Asian American or Pacific Islander ☐☐☐ %
- c. Latino/a or Hispanic ☐☐☐ %
- d. White ☐☐☐ %

8. Other than English, which of the following languages do ***your patients*** speak as their primary language? *Please check* ***all that apply.***

- a. ☐ 1 Spanish
- b. ☐ 1 Chinese (Cantonese or Mandarin)
- c. ☐ 1 Tagalog
- d. ☐ 1 Vietnamese
- e. ☐ 1 Korean
- f. ☐ 1 Russian
- g. ☐ 1 Other language(s) *please specify*_____

9. Other than English, which of the following languages do ***you*** speak with your patients? *Please check* ***all that apply.***

- a. ☐ 1 Spanish
- b. ☐ 1 Chinese (Cantonese or Mandarin)
- c. ☐ 1 Tagalog
- d. ☐ 1 Vietnamese
- e. ☐ 1 Korean
- f. ☐ 1 Russian
- g. ☐ 1 Other language(s) *please specify*_____

10. What percentage of your patients need language interpretation by you, your staff, or anyone else in order to receive health care services?

_____ % need language interpretation

11. ***In the past year***, how often did your practice offer the following types of language interpretation services to your patients that need language interpretation?

	Very Often	Often	Some-times	Rarely	Never
a. Professional language interpretation ***on site***	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Professional language interpretation ***by telephone***	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. Professional language interpretation ***by internet or video***	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. Non-professional interpretation ***by bilingual staff***	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e. Non-professional interpretation ***by patient's friends or family members***	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Section C. Prostate cancer clinical trial referral and recruitment

12. ***In the past year***, have you been a principal investigator or co-investigator in any prostate cancer clinical trials?

- ☐ 0 No
- ☐ 1 Yes If **"Yes"**: In the past year, for how many prostate cancer clinical trials have you been a principal or co-investigator?

  _____ prostate cancer clinical trials

13. As far as you know, are prostate cancer clinical trials conducted at your practice site?

- ☐ 0 No If **"No"**: How far away is the nearest clinical trial site for prostate cancer clinical trials?
  - ☐ 1 Less than a 15-minute drive
  - ☐ 2 15-30 minute drive
  - ☐ 3 30-60 minute drive
  - ☐ 4 Over 1 hour drive
  - ☐ 5 Don't know
- ☐ 1 Yes
- ☐ 77 Don't know

Survey continues on the back...

14. ***In the past year***, how often have you done the following with your prostate cancer patients?

	Very Often	Often	Some-times	Rarely	Never
a. Discussed the possibility of enrolling in prostate cancer clinical trials	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b. Given patients informational resources (e.g., brochures, internet referrals) about prostate cancer clinical trials	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c. Discussed the potential benefits and risks/burdens of a specific prostate cancer clinical trial	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d. Referred patients to prostate cancer clinical trials administered by others	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
e. Enrolled patients in a prostate cancer clinical trial for which you were principal investigator or co-investigator	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

15. In your experience, who typically initiates a discussion about prostate cancer clinical trials? *Please check* ***one*** *answer only.*

- ☐ 1 My patients initiate the discussion
- ☐ 2 I initiate the discussion
- ☐ 3 My patients and I both initiate the discussion
- ☐ 4 I have not discussed clinical trials with my patients

16. ***In the past year***, have you referred or recruited patients to prostate cancer clinical trials sponsored by the following?

	Yes	No
a. National Cancer Institute (NCI)	☐ 1	☐ 0
b. NCI Clinical Trial Cooperative Groups (e.g., ECOG, NSABP)	☐ 1	☐ 0
c. Pharmaceutical / Industry	☐ 1	☐ 0
d. Other sponsors	☐ 1	☐ 0

17. In general, to what degree is each of the following factors a ***barrier for you*** in referring or recruiting prostate cancer patients to clinical trials?

	Major barrier	Moderate barrier	Minor barrier	Not a barrier
a. Trial treatments may be inferior to standard treaments	☐ 1	☐ 2	☐ 3	☐ 4
b. Patients referred to trials may not return to my practice	☐ 1	☐ 2	☐ 3	☐ 4
c. The time and effort required to explain trials to a patient	☐ 1	☐ 2	☐ 3	☐ 4
d. Inadequate reimbursement from research sponsors	☐ 1	☐ 2	☐ 3	☐ 4
e. Lack of dedicated time for research	☐ 1	☐ 2	☐ 3	☐ 4
f. Inadequate information about the trials	☐ 1	☐ 2	☐ 3	☐ 4
g. Patient may not adhere to the study protocol	☐ 1	☐ 2	☐ 3	☐ 4
h. The risks of the trials outweigh the benefits	☐ 1	☐ 2	☐ 3	☐ 4
i. Some trials cannot accommodate non-English speakers	☐ 1	☐ 2	☐ 3	☐ 4
j. Patients don't meet the eligibility or study entry criteria	☐ 1	☐ 2	☐ 3	☐ 4

18. In general, to what degree do you think each of the following factors is a ***barrier for patients*** to participate in prostate cancer clinical trials?

	Major barrier	Moderate barrier	Minor barrier	Not a barrier
a. Patients don't understand what is involved in participating in a clinical trial	☐ 1	☐ 2	☐ 3	☐ 4
b. Patients lack adequate health insurance coverage	☐ 1	☐ 2	☐ 3	☐ 4
c. Patients lack transportation to get to the trial site	☐ 1	☐ 2	☐ 3	☐ 4
d. Patients are reluctant to complete paperwork required in a trial	☐ 1	☐ 2	☐ 3	☐ 4
e. Patients are unable to take time from work, family, or other duties	☐ 1	☐ 2	☐ 3	☐ 4

19. In general, to what degree do you think each of the following factors would be an ***incentive for you*** to refer or recruit prostate cancer patients to clinical trials?

	Major incentive	Moderate incentive	Minor incentive	Not an incentive
a. The clinical trial is likely to improve the patient's quality of life	☐ 1	☐ 2	☐ 3	☐ 4
b. The patient's desire to take advantage of the latest available treatment options	☐ 1	☐ 2	☐ 3	☐ 4
c. Lack of other effective treatment options	☐ 1	☐ 2	☐ 3	☐ 4
d. Prevention of a recurrence	☐ 1	☐ 2	☐ 3	☐ 4
e. Patient would have access to a drug or treatment that is difficult to get outside of a clinical trial	☐ 1	☐ 2	☐ 3	☐ 4
f. I can increase my contact with academic researchers	☐ 1	☐ 2	☐ 3	☐ 4
g. The clinical trial is likely to increase the patient's survival	☐ 1	☐ 2	☐ 3	☐ 4

Section D. Physician demographic characteristics

We would like to ask you a few questions about yourself.

20. In ***what year*** did you graduate from medical school?

_____

21. What is your gender?

- ☐ 1 Female
- ☐ 2 Male

22. In ***which country*** did you graduate from medical school? *Please check* ***one*** *answer only.*

- ☐ 1 United States
- ☐ 2 Another country _____ *please specify*

23. In ***what year*** were you born?

_____

24. Are you Latino/a or Hispanic?

- ☐ 1 Yes
- ☐ 0 No

25. What is your race/ethnicity? *Please check* ***one*** *answer only.*

- ☐ 1 Black or African American
- ☐ 2 Asian, Asian American or Pacific Islander
- ☐ 3 White, European American or Caucasian
- ☐ 4 American Indian or Alaska Native
- ☐ 5 Other _____ *please specify*

You have completed our survey.
Thank you for your time and assistance!

Please return this questionnaire in the envelope provided.

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APPENDIX 6: Survey Analysis Tables

Table 1. Research Team Members Respondent Demographics (N=44)

	N (%)
Female	72.7 (32)
Born in U.S.	68.2 (30)
Job duties (not mutually exclusive)	
Enroll participants	75.0 (33)
Coordinate and schedule participant visits	59.1 (26)
Manage research data	59.1 (26)
Direct, lead, or manage a clinical research program	50.0 (22)
Coordinate the day-to-day non-clinical research operations	50.0 (22)
Maintain regulatory documents	40.9 (18)
Conduct clinical tests or procedures on patients	38.6 (17)
Lead a research team as PI or Co-I	6.8 (3)
Education	
Some college	20.5 (9)
Bachelor's degree	25.0 (11)
Graduate school	52.3 (23)
Years working in research	
<5 years	18.2 (8)
5-10 years	20.5 (9)
>10 years	61.4 (27)

Table 2. Clinical Trial Site Characteristics

	N (%)
Proportion of organization's prostate cancer patients participate in CTs	
Almost all	13.6 (6)
Some	47.7 (21)
Almost none	25.0 (11)
None	13.6 (6)
Participant Population Characteristics (at least 10%)	
Uninsured	13.9 (5)
Insured by Medi-Cal or Medicaid	46.9 (15)
Need interpreter	13.5 (5)
Race/ethnicity	
Hispanic/Latino	47.1 (16)
Asian or Pacific Islander	22.6 (7)
Black/African American	19.4 (6)

Table 3. Clinical Trial Language and Recruitment

Language Interpretation	N(%)
Someone on research team speaks language other than English	76.2 (32)
Types of language interpretation available	
Bilingual staff	100 (25)
Professional by phone	46.9 (15)
Professional onsite	41.2 (14)
Professional by internet/video	10.0 (3)
Documents in other languages	
Experimental Subject's Bill of Rights	54.4 (24)
"Short form" consent forms	22.7 (10)
Directions to study sites	20.5 (9)
Appointment reminders	20.5 (9)
Summaries of trials	15.9 (7)
FAQ sheets about studies	13.6 (6)
Study fliers or posters	0
Recruitment Methods	
Presentations to health providers within organization	68.2 (30)
Posting info on organization's website	52.3 (23)
Presentations to outside health providers	20.5 (9)
Dedicated phone line for patient's questions	13.6 (6)
Presentations to community groups	13.6 (6)
Distributing info at health fairs	13.6 (6)
Videos or CDs	2.3 (1)
Ads in local papers	6.8 (3)
Incentives for Participants	
Complimentary or valet parking	35.7 (15)
Complimentary food or beverages	21.4 (9)
Help with transportation	16.7 (7)
Cash or gift cards/certificates	10.0 (4)
Sponsor-provided gifts (e.g. mugs, pencils)	9.8 (4)

Table 4: RTM Perceived Barriers to Patient Enrollment and Physician Participation

Perceived Barriers for Patients	N(%)
Don't meet eligibility criteria	73.2 (30)
Concerned that risks outweigh benefits	54.8 (23)
Don't understand what clinical trials are	39.0 (16)
Lack adequate insurance coverage	31.7 (13)
Unable to take time from work, family, or other duties	26.8 (11)
Reluctant to complete paperwork	28.6 (12)
Lack transportation	17.1 (7)
Concerned that trials cannot accommodate non-English speakers	9.5 (4)
Perceived Barriers for Physicians	
Concerned that patients will not adhere with study protocol	53.5 (18)
Concerned about time and effort required to explain trials	32.6 (14)
Concerned about inadequate reimbursement from sponsors	30.2 (13)
Don't have adequate time dedicated for research	27.9 (12)
Concerned trial treatment will be inferior to standard	20.9 (9)
Concerned patients referred to trials will not return	20.9 (9)
Don't have adequate information about trials	9.3 (4)

Table 5. Patient Background Characteristics by Race/Ethnicity

	White n=359 n (%)	African Am. n=164 n (%)	Asian n=126 n (%)	Latino n=206 n (%)	Total n=855 n (%)	*P* Value
Background characteristics						
Age Mean (SD)	65.0 (6.0)	62.8 (6.4)	65.8 (6.4)	64.4 (7.5)	64.5 (6.6)	**<0.0001**
Age						
Less than 45 – 54	19 (5.3)	17 (10.4)	7 (5.7)	20 (9.8)	63 (7.4)	
55 – 64	141 (39.5)	77 (47.2)	43 (35.0)	79 (38.7)	340 (40.1)	
65 and over	197 (55.2)	69 (42.3)	73 (59.3)	105 (51.5)	444 (52.4)	**0.03**
Relationship status						
Married or living with partner	282 (79.4)	96 (59.6)	107 (86.3)	153 (75.7)	638 (75.8)	
Single	73 (20.6)	65 (40.4)	17 (13.7)	49 (24.3)	204 (24.2)	**<0.0001**
Education level						
Less than high school	6 (1.7)	11 (6.8)	7 (5.7)	81 (41.1)	105 (12.6)	
High school	38 (10.7)	24 (14.9)	11 (9.0)	36 (18.3)	109 (13.1)	
Some college	68 (19.2)	70 (43.5)	14 (11.5)	41 (20.8)	193 (23.1)	
College graduate	242 (68.4)	56 (34.8)	90 (73.8)	39 (19.8)	427 (51.2)	**<0.0001**
Nationality						
U.S. Born	315 (88.7)	150 (93.2)	35 (28.2)	78 (38.6)	578 (68.6)	
Foreign Country	40 (11.3)	11 (6.8)	89 (71.8)	124 (61.4)	264 (31.4)	**<0.0001**
Employment Status (includes full and part time)						
Employed	197 (58.5)	85 (55.6)	53 (50.0)	91 (46.4)	426 (53.8)	
Unemployed	140 (41.5)	68 (44.4)	53 (50.0)	105 (53.6)	366 (46.2)	**0.05**
Location						
Region						
Northern CA	224 (62.4)	89 (54.3)	82 (65.1)	107 (51.9)	502 (58.7)	
Southern CA	135 (37.6)	75 (45.7)	44 (34.9)	99 (48.1)	353 (41.3)	**0.03**
Access to care						
Health Insurance type (not mutually exclusive)						
Government						
Yes	183 (52.6)	79 (50.0)	63 (51.6)	106 (53.5)	431 (52.2)	
No	165 (47.4)	79 (50.0)	59 (48.4)	92 (46.5)	395 (47.8)	0.92
Private insurance						
Yes	301 (86.7)	126 (79.7)	86 (70.5)	135 (68.5)	648 (78.6)	
No	46 (13.3)	32 (20.3)	36 (29.5)	62 (31.5)	176 (21.4)	**<0.0001**
Health Literacy Scale						
Low Literacy	11 (3.1)	9 (5.7)	19 (15.6)	42 (20.7)	81 (9.7)	
Medium Literacy	161 (45.6)	89 (56.0)	61(50.0)	124 (61.1)	435 (52.0)	
High Literacy	181 (51.3)	61(38.4)	42 (34.4)	37 (18.2)	321 (38.4)	**<0.0001**
Prior health research experience						
Participated in health research study						
Never	267 (74.4)	86 (52.4)	107 (84.9)	173 (84.0)	633 (74.0)	
At least once	41 (11.4)	32 (19.5)	11 (8.7)	24 (11.7)	108 (12.6)	
More than once	51 (14.2)	46 (28.0)	8 (6.3)	9 (4.4)	114 (13.3)	**<0.0001**
Disease characteristics						
Age at diagnosis Mean (SD)	62.1 (5.9)	59.9 (6.5)	62.7 (6.3)	61.1 (7.0)	61.5 (6.4)	**<0.0001**
Gleason score						
Scores 1-6	161 (45.0)	60 (37.0)	54 (43.2)	94 (46.3)	369 (43.5)	
Scores 7-10	197 (55.0)	102 (63.0)	71 (56.8)	109 (53.7)	479 (56.5)	0.29

Table 6. Patient Willingness to Participate in a Prostate Cancer Clinical Trial by Sociodemographics

	Willing n=326 n (%)	Total n=855 n	*P* Value
Race/Ethnicity			
White	118 (32.9)	359	
African American	64 (39.0)	164	
Asian America	37 (29.4)	126	
Latino	107 (51.9)	206	**<0.0001**
Background characteristics			
Age			
Less than 45 - 54	20 (31.7)	63	
55 - 64	125 (36.8)	340	
65 and over	180 (40.5)	441	0.30
Relationship status			
Married or living with partner	241 (37.8)	638	
Single	83 (40.7)	204	0.46
Education level			
Less than high school	63 (60.0)	105	
High school	42 (38.5)	109	
Some college	67 (34.7)	193	
College graduate	148 (34.7)	427	**<0.0001**
Nationality			
U.S. Born	202 (34.9)	578	
Foreign Country	122 (46.2)	264	**0.002**
Employment Status (includes full and part time)			
Employed	168 (39.4)	426	
Unemployed	137 (37.4)	366	0.56
Location			
Region			
Northern CA	192 (38.2)	502	
Southern CA	134 (38.0)	353	0.93
Access to care			
Health Insurance type (not mutually exclusive)			
Government			
Yes	183 (42.5)	431	
No	134 (33.9)	395	**0.01**
Private insurance			
Yes	235 (36.3)	648	
No	81 (46.0)	176	**0.02**
Health Literacy Scale			
Low Literacy	39 (48.1)	81	
Medium Literacy	175 (40.2)	435	
High Literacy	109 (34.0)	321	**0.03**
Prior health research experience			
Participated in health research study			
Never	239 (37.8)	633	
At least once	40 (37.0)	108	
More than once	47 (41.2)	114	0.76

Table 7. Factors that Affect Patient Willingness to Participate in a Prostate Cancer Clinical Trial

	Odds of Willingness to participate	*P* Value
Race/Ethnicity		
White (reference)	-	-
African American	1.4 (0.9 – 2.2)	0.14
Asian American	0.8 (0.5 – 1.3)	0.80
Latino	1.8 (1.1 – 2.8)	**0.01**
Background characteristics		
Age		
Less than 45 - 54	0.9 (0.3 – 2.5)	0.77
55 - 64	1.2 (0.6 – 2.1)	0.62
65 and over (reference)	-	-
Relationship status		
Married or living with partner	1.0 (0.7 – 1.4)	0.82
Single (reference)	-	-
Education level		
Less than high school	1.7 (1.0 – 3.1)	0.06
High school	1.0 (0.6 – 1.7)	0.90
Some college	0.9 (0.6 – 1.4)	0.67
College graduate (reference)	-	-
Employment Status (includes full and part time)		
Employed	1.7 (1.2 – 2.4)	**0.01**
Unemployed (reference)	-	-
Location		
Region		
Northern CA	0.9 (0.7 – 1.3)	0.61
Southern CA	-	-
Access to care		
Health Insurance type (not mutually exclusive)		
Government		
Yes	1.7 (1.1 – 2.7)	**0.03**
No (reference)	-	-
Private insurance		
Yes	0.8 (0.5 – 1.3)	0.37
No (reference)	-	**-**
Health Literacy Scale		
Low Literacy	1.3 (0.7 – 2.4)	0.43
Medium Literacy	1.2 (0.8 – 1.6)	0.33
High Literacy (reference)	-	-
Prior health research experience		
Participated in health research study		
Never (reference)	-	-
At least once	1.0 (0.6 – 1.5)	0.83
More than once	1.4 (0.9 – 2.2)	0.14
Disease characteristics		
Mean age at diagnosis (SD)		
-	-	-
61.8 (6.3)	1.0 (1.0 – 1.1)	0.77
Gleason score		
Scores 1-6 (reference)	-	-
Scores 7-10	0.8 (0.6 – 1.1)	0.28

Table 8. Physician Respondent Demographics

	N (%)
Gender	
Female	19 (7.4)
Male	234 (91.4)
Latino or Hispanic	8 (3.1)
Race/Ethnicity	
White	156 (60.9)
Asian American	82 (32.0)
Latino	8 (3.1)
African American	4 (1.6)
Other	1 (0.4)
Primary Medical Specialty	
Urology	139 (54.3)
Primary Care	56 (21.9)
Radiation Oncology	42 (16.4)
Hematology/Oncology	18 (7.0)
Other	1 (0.4)
Location of Medical School	
United States	218 (85.2)
Another county	35 (13.8)

Table 9. Patient and Primary Practice Site Characteristics

	N (%)
Primary Practice Site	
Group and Community Practices	121 (47.3)
Group model HMO (e.g., Kaiser Permanente)	74 (28.9)
Hospitals	31 (12.1)
University/Medical School-based Hospital	30 (11.7)
Language Interpretation	
Use of Language Interpretation Types (used very often)	
Professional by Telephone	52 (20.3)
Bilingual Staff	46 (18.0)
Professional Onsite	40 (15.6)
Professional by Internet or Video	5 (2.0)

Table 10. Prostate Cancer Clinical Trial Referral and Recruitment

	N (%)
In the past year, how often have you done the following with your prostate cancer patients? (answered very often or often)	
Discussed the possibility of enrolling in prostate cancer clinical trials	52 (20.3)
Given participants informational resources about prostate cancer clinical trials	42 (16.4)
Discussed the potential benefits and risks/burdens of a specific prostate cancer clinical trial	36 (14.1)
Referred patients to prostate cancer clinical trials administered by others	29 (11.3)
Enrolled patients in a prostate cancer clinical trial for which you were principle investigator or co-investigator	21 (8.2)

Table 11. Physician Perceived Barriers to Patient Enrollment and Physician Participation

Perceived Barriers for Patients	N (%)
Don't understand what is involved in participation	153 (69.8)
Unable to take time from work, family, or other duties	130 (50.8)
Lack transportation to get to the trial site	116 (45.3)
Reluctant to complete paperwork required in a trial	105 (41.0)
Lack adequate health insurance coverage	96 (37.5)
The risks of trials outweigh the benefits	47 (18.4)
Trials cannot accommodate non-English speakers	47 (18.4)
Concerned that patients will not adhere with study protocol	40 (15.6)
Perceived Barriers for Physicians	
Don't have adequate information about trials	120 (46.9)
Patients don't meet the eligibility or study entry criteria	111 (43.4)
Don't have adequate time dedicated for research	99 (38.7)
Concerned about time and effort required to explain trials	86 (33.6)
Concerned trial treatment will be inferior to standard care	61 (23.8)
Concerned about inadequate reimbursement from sponsors	44 (17.2)
Concerned patients referred to trials will not return	23 (9.0)

APPENDIX 7: 2011 IMPaCT Conference Poster

Assessment of the Clinical Trial Environment in the Recruitment of Minorities into Prostate Cancer Clinical Trials

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Background

Clinical trials are the major channel for translating treatment-related discoveries in prostate cancer care into the clinical environment. Enhanced participation by minorities in these trials is necessary to assess the effectiveness of advances in prostate cancer care among major subpopulations and to ensure equity in the distribution of new treatment benefits. However, it has been recognized the low proportions of patients with cancer that are recruited into trials.

Recruitment for clinical trials is a multifaceted process that involves multiple components (see Figure 1). While most studies have highlighted the role of physicians and patients play in the reduced participation of minorities, the specific role of the clinical trials sites has not been firmly established. Language competence of the clinical trials sites and their outreach efforts are key in the recruitment of minorities, particularly those who are not fluent in English.

The overall study, funded by the DoD Prostate Cancer Research Program, examines multiple influences on minority participation. This presentation will focus on the clinical trial site's characteristics related to minority participation among clinical trial sites.

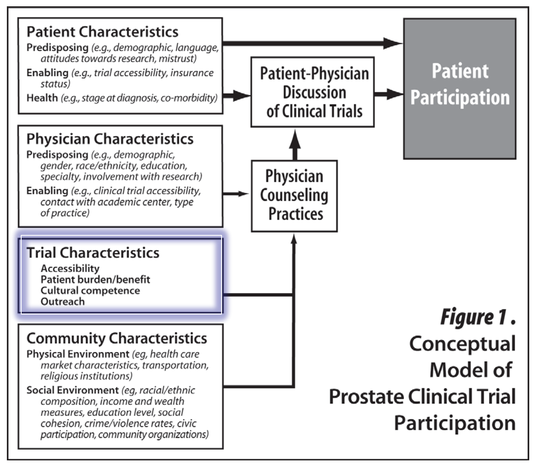

Figure 1. **Conceptual Model of Prostate Clinical Trial Participation**

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Figure 2. Targeted CCR regions. Region 1: Monterey, San Benito, Santa Clara and Santa Cruz counties; Region 8: Alameda, Contra Costa, Marin, San Francisco, and San Mateo counties; Region 9: Los Angeles county.

Methods

- Identified 69 prostate cancer clinical trials recruiting participants in 2008 from three California Cancer Registry Regions through National Cancer Institute website.
- Eligible trials were located in CCR regions 1, 8, and 9 (see Figure 2); were conducted in 2008; included prostate cancer treatment; and were funded by the NIH and/or the pharmaceutical industry.
- Identified all 77 sites implementing these trials and the RTMs involved in these studies.
- Collected general information about trials, sites, and RTMs from NCI website and site web pages.
- Research assistants attempted to contact one RTM from each site to complete a brief survey over the phone.
- Surveys were conducted from April 2010 through January 2011. The survey was also available by mail, fax, or email, depending on preference.

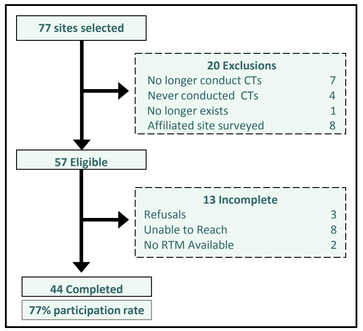

Figure 3. Clinical Trial (CT) Research Team Member (RTM) Eligibility and Participation.

Results

Research Team Members Demographics (n=44)	
Female	72.7 (32)
Born in U.S.	68.2 (30)
Job duties	
Lead a research team as PI or Co-I	6.8 (3)
Direct, lead, or manage a clinical research program	50.0 (22)
Coordinate the day-to-day non-clinical research operations	50.0 (22)
Enroll participants	75.0 (33)
Coordinate and schedule participant visits	59.1 (26)
Manage research data	59.1 (26)
Conduct clinical tests or procedures on patients	38.6 (17)
Maintain regulatory documents	40.9 (18)
Education	
Some college	20.5 (9)
Bachelor's degree	25.0 (11)
Graduate school	52.3 (23)
Years working in research	
<5 years	18.2 (8)
5-10 years	20.5 (9)
>10 years	61.4 (27)

Proportion of prostate cancer patients participate in CTs	
Almost all	13.6 (6)
Some	47.7 (21)
Almost none	25.0 (11)
None	13.6 (6)
Participant Population Characteristics (at least 10%)	
Uninsured	13.9 (5)
Insured by Medi-Cal or Medicaid	46.9 (15)
Need interpreter	13.5 (5)
Race/ethnicity	
Black/African American	19.4 (6)
Asian or Pacific Islander	22.6 (7)
Hispanic/Latino	47.1 (16)

Language Accommodation	
Someone on research team speaks language other than English	76.2 (32)
Types of language interpretation available	
Bilingual staff	100 (25)
Professional onsite	41.2 (14)
Professional by phone	46.9 (15)
Professional by internet/video	10.0 (3)
"Short form" consent forms	22.7 (10)
Experimental Subject's Bill of Rights	54.4 (24)
Summaries of trials	15.9 (7)
FAQ sheets about studies	13.6 (6)
Directions to study sites	20.5 (9)
Appointment reminders	20.5 (9)
Study fliers or posters	0

Recruitment Efforts	
Videos or CDs	2.3 (1)
Ads in local papers	6.8 (3)
Dedicated phone line for patient's questions	13.6 (6)
Presentations to community groups	13.6 (6)
Presentations to health providers within organization	68.2 (30)
Presentations to outside health providers	20.5 (9)
Distributing info at health fairs	13.6 (6)
Posting info on organization's website	52.3 (23)

Results (continued)

Incentives for Participants	
Complimentary or valet parking	35.7 (15)
Help with transportation	16.7 (7)
Cash or gift cards/certificates	10.0 (4)
Complimentary food or beverages	21.4 (9)
Sponsor-provided gifts (e.g. mugs, pencils)	9.8 (4)

Perceived Barriers for Patients	
Don't meet eligibility criteria	73.2 (30)
Concerned that risks outweigh benefits	54.8 (23)
Don't understand what clinical trials are	39.0 (16)
Lack adequate insurance coverage	31.7 (13)
Unable to take time from work, family, or other duties	26.8 (11)
Perceived Barriers for Physicians	
Concerned that patients will not adhere with study protocol	53.5 (18)
Concerned about time and effort required to explain trials	32.6 (14)
Concerned about inadequate reimbursement from sponsors	30.2 (13)
Don't have adequate time dedicated for research	27.9 (12)
Concerned trial treatment will be inferior to standard	20.9 (9)

Conclusions

Research team members report:

- Most patients do not participate in CTs, particularly minority patients
- Most CT sites have language interpretation available, but primarily by bilingual staff
- The majority of printed CT materials are only available in English
- Recruitment efforts are primarily focused on internal presentations and posting on the site's web page
- Participant incentives are limited, aside from parking discounts
- Patients do not participate because they don't meet eligibility criteria or they are concerned that the risks outweigh the benefits
- Physicians do not recruit because they are concerned patients will not adhere to the CT protocol or they are concerned about the amount of time it will take to explain the trial

Impact

This study extends our current state of knowledge about the effects of clinical trial site characteristics on referral and participation of minorities. Results will contribute to the development of interventions aimed at clinical trials sites that address specific barriers associated with the clinical trial site.